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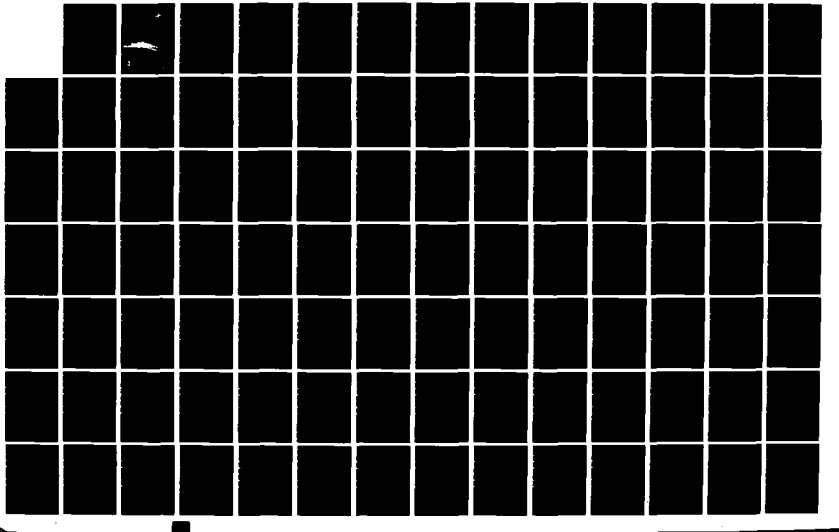

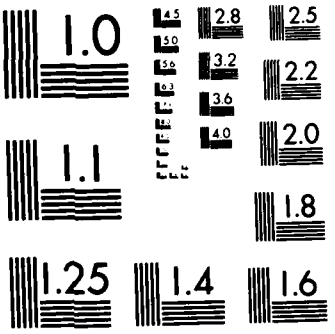

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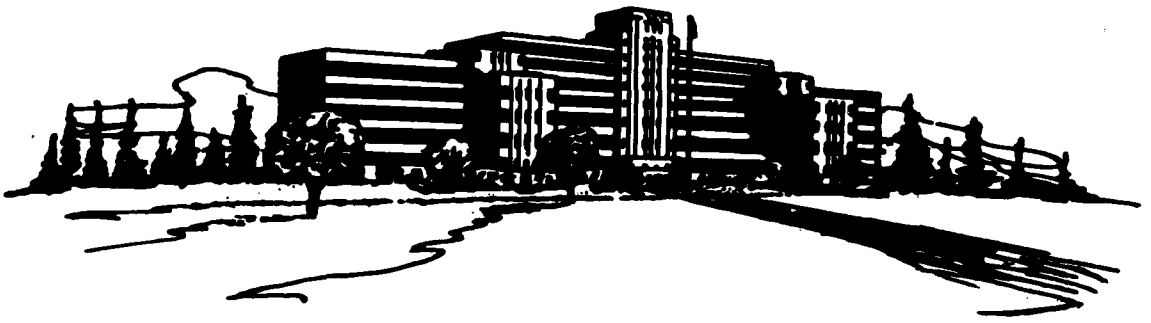
Laboratory
Report No. 20

CLINICAL INVESTIGATION PROGRAM ANNUAL PROGRESS REPORT

AD-A154 658

30 September 1984



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DEPARTMENT OF CLINICAL INVESTIGATION

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DEPARTMENT OF CLINICAL INVESTIGATION

REPORT CONTROL SYMBOL MED-300

CLINICAL INVESTIGATION PROGRAM
ANNUAL PROGRESS REPORT

30 September 1984

CLINICAL INVESTIGATIONS (U)

FITZSIMONS ARMY MEDICAL CENTER

AURORA, COLORADO 80045-5000

FOREWORD

This report identifies the research activities conducted by Fitzsimons Army Medical Center investigators through protocols approved by the Institutional Review Committee and registered with the Department of Clinical Investigation during Fiscal Year 1983 along with other known presentations and publications by FAMC professional staff.

The research protocols described in this report were conducted under the provisions of AR 40-38, Clinical Investigation Program, AR 40-7, Use of Investigational Drugs in Humans, AR 70-25, Use of Volunteers as Subjects of Research, and HSC Reg 40-23, as amended, Management of Clinical Investigation Protocols and Reports, to insure the medical safety, well being, preservation of rights and dignity of human subjects who participated in these investigations.

In conducting the research described in this report, the investigator(s) adhered to AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs and the "Guide for Laboratory Animal Facilities and Care", as promulaged by the Committee or the Guide for Laboratory Animal Resources, National Academy of Sciences, National Research Council.

The Department of Clinical Investigation is especially grateful to BRIGADIER GENERAL Philip K. Russell, MC, Commanding General of Fitzsimons Army Medical Center, his professional and administrative staff, and to the Commanding Officers and staffs of other supporting activities for the cooperation and assistance provided this Department of Clinical Investigation in our efforts to accomplish our mission. Finally, I would like to recognize the outstanding work, dedication, and wholehearted corroboration of my entire staff. I would especially like to thank my Protocol/Editorial Assistant, Ms. Val McCrill and Mrs. Lilly C. Montoya, Secretary, without whose assistance and support this report would not have been possible.

Donald G. Corby

DONALD G. CORBY, M.D.
Colonel, MC
Chief, Department of Clinical Investigation

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DETAIL SUMMARY SHEETS

MEDICINE

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Ongoing (O), Completed (C), Terminated (T), Published (P) or Submitted for Publication (SP), Presentations (PR).

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Kidd, G.S., Smith, C.E. and Wray, H.L.: Effect of Thyroid Status on the Renal Responses to Vasopressin (Submitted for Publication, J Clin Endocrinol Metab, 1984)

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Bennion, S.D., Fitzpatrick, J.E., Harbell, J., Swanson, E. and O'Barr, T.: The Effect of UVB on 6-Keto-PGF production by Cultured Human Endothelial Cells. J Invest Dermatol 82:428a, 1984. (C)

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Newell, J.D., Thomas, H.M. and Maurer, J.W.: Computed Tomographic Demonstration of Displaced Right Upper Lobe Bronchus in an Adult Woman with Congenital Heart Disease. CT: The J of Computed Tomography 8:75-79, 1984.

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Svinarich, J.T., Tai, D.Y. and Sung, R.J.: Is Beta-Adrenergic Blockade Contraindicated in Wolff-Parkinson-White Patients Prone to Atrial Fibrillation? Circ (in press).

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PUBLICATIONS

DEPARTMENT OF MEDICINE

Allergy Service

Brown, J.S., Ledoux, R., Tipton, W.R. and Nelson, H.S.: An Investigation of the Immunologic Reaction to Human Serum Albumin. Ann Allergy 52:221, 1984. (C)

Kray, K.T., Squire, E.N., Tipton, W.R., Selner, J.C., O'Day, J. and Nelson, H.S.: Cromolyn Sodium in Seasonal Allergic Conjunctivitis. Ann Allergy 52:223, 1984. (C)

Long, W.F., Taylor, R.J. and Nelson, H.S.: Histamine and Morphine or Antigen Skin Test on the Effect of Antihistamines. Ann Allergy 52:241, 1984. (C)

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Nelson, H.S.: Combination of Oral Theophylline and Aerosolized Beta$_2$-agonists, in Jonkman, J.H.G, Jenne, J.W., Simons, F.E.R., eds: Sustained Release Theophylline in the Treatment of CRAO, International Workshop Mont Ste Marie, Canada, Exerpta Medica, 1984, p 181-7. (C)

Nelson, H.S.: Routine Sinus Roentgenograms and Chronic Urticaria. JAMA 251:1680-1, 1984.

Nelson, H.S.: What is Atopy? Sidestepping Semantics. Postgrad Med 76:118-129, 1984.

Nelson, H.S.: Gastroesophageal Reflux and Pulmonary Disease. J Allergy Clin Immunol 73:547-556, 1984.

Taylor, R.J., Long, W.F. and Nelson, H.S.: Development of Subsensitivity to Antihistamines. Ann Allergy 52:240, 1984.

Tipton, W.R.: Evaluation of Skin Testing in the Diagnosis of IgE Mediated Disease. Symposium on Pediatric Allergy. Pediatric Clinics of North America. Vol. 30, no. 5, 785-793, 1983.

(C) Direct result of approved registered protocol.

PUBLICATIONS

Other protocols yieldiing interesting results during FY 84 were those involving plasmids of Legionella pneumophila and Campylobacter spp., and one testing a new method of rapidly demonstrating vaginal colonization by Group B streptococci in women experiencing premature labor.

LTC Engelkirk and Mr. Steven Koester (of the Immunology Service, DCI) have submitted, to the Journal of Medical Technology, a review article describing putative functions of eosinophils. The article features eight previously unpublished transmission electron micrographs.

Funding

The OMA costs have not been itemized by protocol number because it is not feasible or practical to do so.

MEDCASE item(s) puchased for protocols and general laboratory use are listed as follows:

ITEM	COST
Cryolathe for Ophthamology	$66,500
Waters HPLC	$63,000
J6M Beckman Centrifuge	$17,500
J6M Beckman Centrifuge	$18,000
Beckman Airfuge	$9,995
Radiomatic Detector	$21,000

Studies on the vitamin D-calcium metabolism interrelationship in the chick model has progressed to the studying of vitamin D metabolites and their effects on calcium transport and uptake by the intestinal epithelial cell membranes.

Cell Physiology Service

This newly established service was created to support research on normal and disease state human tissues using *in vitro* and heterotransplantation model systems. To these ends, a second laminar hood has been added to the tissue culture clean room. Two CO_2 humidified incubators were also added to grow normal dermal cell types. A second sterile room was added to the athymic nude mouse breeding and holding facility to meet protocol support requirements. The electron microscopy capabilities have also been greatly increased by the installation of a Siemens TBM.

Immunology Service

A flow cytometer (cell sorter) has been procured and procedures for performing lymphocyte phenotyping have been implemented. Development of procedures for utilizing flow cytometry for detecting antiplatelet antibodies, quantitating immune complexes, and quantitating antitetanus antibodies are also being performed to determine the capability of flow cytometric procedures for measuring neutrophil function.

Microbiology Service

The diagnostic mycobacteriology laboratory continued to achieve perfect scores on the quarterly CAP proficiency surveys during FY 84, bringing its record to ten consecutive perfect scores. During FY 84, a total of 2983 specimens were received for mycobacteriology processing (AV = 249/mo.).

Considerble progress was made on a research protocol designed to determine the *in vitro* effects of various humoral and cellular immune components of rats and humans on *Giardia lamblia* trophozoites. Two posters were presented during FY 84, an additional poster has been accepted for presentation in FY 85, an electron micrograph has been accepted for publication on the cover of *ASM News* (a monthly publication of the American Society for Microbiology, circulation 30,000), and three manuscripts are in preparation. A cytotoxicity assay was developed which utilizes the radionuclide, 111-Indium. It was also demonstrated that human peripheral blood eosinophils are capable of ingesting *G. lamblia* trophozoites, and that they deposit the enzyme, peroxidase, onto the surfaces of partially and fully ingested trophozoites.

steam sterilizer has been installed and has proven to be a valuable resource. Air locks have been installed on the cage washer to prevent the simultaneous opening of both doors thus preventing the contamination of the clean side storage area. The cage washer has been equipped with a constant voltage transformer to prevent voltage surges to the control panel which resulted in the burnout of several circuit boards. The service has requested the procurement of modular housing units for the purpose of housing domestic (farm) animals. The increased use of domestic animals will be brought about due to the decreased use of dogs and cats for teaching and training.

The Service also obtained a renovated blood gas analyzer from Respiratory Therapy and an ACA Automated Chemanalyzer from USAMEOS.

The Service was site visited by the American Association for the Accreditation of Laboratory Animal Care (AAALAC) and received provisional accreditation pending the correction of cited deficiencies. The Service has corrected the deficiencies, notified AAALAC of the corrections that have been made and expects to receive full accreditation within several months.

Five Animal Resources Service personnel are participating in American Association for Laboratory Animal Science Training which will lead to their certification as Laboratory Animal Technologists. Larry Jones, Animal Resource Facility manager received the Commander's Award for his excellent work in facility startup operations and his work in preparation for the AAALAC inspection.

Biochemistry Service

The implication of prostaglandins as mediators of the early stage of UVB-induced erythema has been examined. Specifically, the ability of cultured human microvasculature endothelial cells to produce prostacylin (PGI_2) in response to UVB was studied. UVB irradiated cells were found to produce progressively greater amounts of PGI_2 as the intensity of radiation was increased.

The generation of thromboxane A_2 (TxA_2) by platelets and PGI_2 by aorta rings from rats made hypothyroid with ^{131}I was documented over a 16 week period. By comparison with euthyroid animals, the hypothyroid state resulted in a decrease in platelet TxA_2 and a concomitant increase in spontaneous PGI_2 formation by aorta rings. These prostaglandin alterations are in keeping with the platelet dysfunction seen in human hypothyroidism and may contribute to the acute protective effect of hypothyroidism on unstable angina.

Description	Grade	MOS	Br	Auth	Req	Act	Name
Microbiologist	11	0403	GS	2	2	2	Lima Paine
Microbiologist	09	0403	GS	3	6	4	Koester Morse Nelson Wuerz
Med Technologist	11	0644	GS	0	1	1	Rush
Med Technician	07	0645	GS	2	2	2	Hakes Ramirez
Research Chem	09	1320	GS	3	4	4	Noble Swanson Waldrup Feuerstein
Bio Lab Tech	08	0404	GS	1	1	1	Jones
(animal)	09	0404	GS	1	1	1	Mercill
Ed Asst	06	0318	GS	1	1	1	McCrill
Animal Caretaker	05	7706	WG	1	3	2	Slatton Hitchcock
Clerk-Steno	05	0318	GS	1	1	1	Montoya

	FY 81	FY 82	FY 83	FY 84
Civilian Pay	474,832	526,991	565,020	553,099
Travel	7,629	5,350	3,901	6,292
Supplies	222,999	239,833	249,086	210,167
Equipment	153,912	201,002	200,395	148,571
Contracts	23,540	25,592	11,392	18,864
Other(Military)	417,320	470,174	439,878	405,432

Animal Resources Service

The management and staff of the Animal Resources Service continue to make improvements in the operating efficiency of the new 7,000 square foot animal housing facility. A new

Use of Investigational Drugs in Humans; AR 70-25, Use of Volunteers as Subjects in Research; AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports, as amended; FAMC Reg 15-2, Institutional Review Committee. This Department provides guidance, assistance, and coordinates the FAMC program with higher headquarters and other facilities.

Manpower: Current authorized strength is outlined.

Description	Grade	MOS	Br	Authorized	Req	Act	Name	Rank
Chief Dept Clin Inv	06	60P9B	MC	1	1	1	Corby	COL
C, Micro Svc	04	68A00	MSC	1	1	1	Engelkirk	LTC
Lab Res Mgr	03	68F00	MSC	0	1	1	Quigg	MAJ(P)
C, Biochem Svc	03	68C00	MSC	1	1	0		
C, Immunol Svc	03	68E00	MSC	1	1	1	Rickman	CPT
C, Cell Phys. Svc.	03	68J00	MSC	1	1	1	Ferris	CPT
C, Animal Res Svc	04	68F00	VC	1	1	1	McCullen	CPT(P)
NCOIC-Med Lab	E7	92B4R		1	1	1	Engle	SFC
Sr Med Lab SP	E6	92B3R		1	1	1	Fernandez	SGT
Operating Rm Sp	E5	91D2R		1	1	1	Dugan	SP5
Bio Sci Asst	E5	01H2R		1	1	1	Kramer	SP5
Bio Sci Asst	E5	01H3R		1	1	1	Chadwick	SP6
Bio Sci Asst	E5	01H2R		1	1	1	Jones	SP5
Bio Sci Asst	E4	01H3R		1	1	1	Sanders	SP4
Vet Sp	E5	91T2R		1	2	1	Barrett	SP5
Vet Sp	E3	91T1R		0	0	1	Lamb	PFC
Vet Sp	E3	91T2R		0	0	1	Phillips	PFC
Supv Res Chem	13	1320		1	1	1	O'Barr	

UNIT SUMMARY

Clinical Investigation Program, FAMC

Clinical Investsigation efforts by FAMC personnel in FY 84 culminated in the publication of 121 articles and 124 presentations and lectures at national, international, and regional scientific meetings. As of 30 September 1984, there were 128 research protocols on the DCI register. Of these, 88 projects were ongoing and 40 were new registrations.

Objectives:

To encourage the performance of clinically-oriented investigation by personnel assigned to the Fitzsimons Army Medical Center (FAMC). To aid in the planning, development, support, and execution of experimental clinical studies, both in patients and by directly related laboratory work, into the clinical problems of significant concern in the health care of members of the military community. To provide physician experience in research and investigative procedures by furnishing a highly educated and trained staff of specialists, laboratory facilities, administrative services and funding for: supplies, equipment, consultants, publications and reprints. To achieve continuous improvement in the quality of patient care by providing an atmosphere of inquiry, maintaining high professional standing and accreditation of advanced health programs.

The Clinical Investigation Program differs from Medical Research and Development in that the emphasis is on the health care problems existing in our patient populations, i.e.; active duty, retired, and dependents and not solely on medical problems affecting combat readiness and the fighting strength. It is, by its nature, an integral part of the triad of patient care and medicine. It promotes and supports the finest ideals and traditions of Military Medicine and enhances the vitality of the teaching programs which in turn elevates the standard of medical care. The research program operates on the premise that all approved protocols will be supported to the fullest extent allowed by current funding. This concept allows for a larger number of physicians and ancillary personnel to participate in research rather than as in the grant system used elsewhere. This means that virtually every investigator is given a chance to pursue his research without having to compete for funds with "established" names in the field.

Technical Approach:

This support, direction and management is carried out under the aegis of AR 40-38, Clinical Investigation Program; AR 40-7,

UNIT SUMMARY

Ongoing (O), Completed (C), Terminated (T), Published (P), or Submitted for Publication (SP), Presentations (PR).

Ongoing (O), Completed (C), Terminated (T), Published (P), or Submitted for Publication (SP), Presentations (PR).

Sjoberg, R.J., McMillan, V.M., Bartram, L.S. and Copley, J.B.: Renal Failure with Minimal Change Nephrotic Syndrome: Reversal with Hemodialysis. Clin Nephrology 20(2):98:100, 1983.

Sjoberg, R.J., Kidd, G.S. and Hofeldt, F.D.: Granuloma Annulare and Carbohydrate Tolerance. (Abst) Diabetes 33(Suppl 1):106A, 1984.

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Dunn, M.A. and Brewer, T.G.: Non-viral Liver Infections. The Liver Annual (4/1984). (IM Arias, M. Frenkel and JMP Wilson, Editors) Elsevier-North Holland, New York, 1984.

Moses, F.M., Wong, R.K.H. and Peura, D.A.: Squamous Cell Carcinoma of the Esophagus Associated with Peptic Duodenal Ulcer. Amer J Gastro 78:712-4, 1983.

Moses, F.M., Peura, D.A. and Johnson, L.F.· Triple Lumen Pylorus, A Complication of Peptic Ulcer Disease: Case Report. Gastrointestinal Endoscopy (in press).

Moses, F.M., Peura, D.A., Wong, R.K.H. and Johnson, L.F.: Palliative Dilation of Esophageal Carcinoma. Gastrointestinal Endoscopy (in press).

McNally, P.R., Herrera, J.L., Engelkirk, P.G., Visvesvara, G.S. and Brewer, T.G.: Prospective Evaluation of Immunofluorescent Antibody (IFA) Testing in the Diagnosis of Giardiasis. Manuscript submitted for publication. (C)

Shaw, C.T.: Marked Elevation of Serum Transaminases Associated with Extrahepatic Biliary Tract Disease. Manuscript submitted for publications.

Nephrology Service

Copley, J.B. and Hasbargen, J.A.: "Primary" Hematuria: A Prospective Evaluation (Abstract) Kidney International (In Press)

Neurology Service

Hurst, D.L.: Metatarsus Adductus in Two Brothers with Aarskog Syndrome. J Med Genetics 20:477, 1983.

(C) Direct result of approved registered protocol.

Hurst, D.L.: Valproic Acid Embryopathy. (Abstract)

Hurst, D.L.: Intraventyricular Rupture of a Middle Cerebral Artery Aneurysm. (Abstract)

Hurst, D.L.: Distal Fibroma - Facial Focal Atrophy Syndrome - A New Neurocutaneous Disorder. (Abstract)

Hurst, D.L. and Hurst, M.J.G.: Bromide Poisoning in the Ordeal of Gilbert Pinfold. (Abstract)

Hurst, D.L.: The Use of Imipramine as an Anticonvulsant for Minor Motor Seizures. (Abstract)

Murphy, M.G., Hurst, D.L., Merenstein, G.B. and Pierce, J.R.: Mortality and Morbidity in Surviving Twin after Single Intrauterine F~tal Demise. (Abstract).

Wolf, B., Grier, R.E., Allern, R.J., Goodman, S.I., Kien, C.L., Parker, W.D., Howell, D.M. and Hurst, D.L.: Phenotypic Variation in Biotinidase Deficiency. J Pediatr 103:233-237, 1983.

Pulmonary Disease

Perry, M.E., Blue, P.W. and Kindig, N.B.: Pressure Waveform Correlation with Xenon Washout in a Physical Model of High Frequency Oscillation. Syllabus of the Postgraduate Course on High Frequency Ventilatin. P 127-128, 1983, Memorial Sloan Kettering Cancer Center. (C).

Perry, M.E., Blue, P.W., Kindig, N.B. and Ghaed, N.: Gas Washout Pressure Waveform Characteristics of High Frequency Oscillation. Crit Care Med 12: Sept 1984. (C).

Schlachter, M.D.: Plethysmographic Determination of Lung Mechanics During Frequency Jet Ventilation with CPAP. (Abst) Syllabus of the Postgraduate Course on High Frequency Ventilation. p 81-82 1983, Memorial Sloan Kettering Cancer C~nter. (C).

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Rheumatology

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DEPARTMENT OF SURGERY

Orthopedic Service

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PRESENTATIONS

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(C) Direct result of approved registered protocol.

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(C) Direct result of approved registered protocol.

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Florek, R.C.: Potassium Loading to Unmask Wolff-Parkinson-White Syndrome. Presented: Army Cardiology Meeting, Walter Reed Army Medical Center, Washington, D.C., May 1984.

Jordan, L.W. and Wortham, D.C.: Thallium Exercise Scintigraphy in the Evaluation of Army Active Duty Personnel Over the Age of Forty. Presented: Annual Meeting of the Association of Military Cardiologists, Washington, D.C., 1984.

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Raible, S.J., Schaaf, M., Oetgen, W.J. and Smallridge, R.C.: Acromegaly and the Heart: Evaluation of Cardiac Function by Radionuclide Angiocardiography. Presented: Army Cardiology Meeting, Walter Reed Army Medical Center, Washington, D.C., May 1984.

Svinarich, J.T.: Exercise Training. Current Concepts in Internal Medicine. Presented: San Francisco, CA, October 1983.

Svinarich, J.T.: Electrophysiologic Demonstration of Concealed Conduction in Anomalous Atrioventricular Bypass Tracts. American College of Cardiology Scientific Sessions, Dallas, TX, March 1984.

Svinarich, J.T., White, C.J. and Watson, T.D.: Coronary Artery Aneurysm as a Complication of Balloon Angioplasty: Report of Four Cases., Army Cardiology Meeting, Walter Reed Army Medical Center, Washington, D.C., May 1984.

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Bennion, S.D., Fitzpatrick, J.E., Harbell, J., Swanson, E. and O'Barr, T.: The Effect of UFB on 6-keto-PGF_1 Production by Cultured Human Endothelial Cells. Presented: SID Meeting, Washington, D.C., May 1984. (C).

Fitzpatrick, J.E.: Current Management of Sexually Transmitted Disease. Presented: 31st Annual Family Pract Seminar, Estes Park, CO, 15 June 1984.

Fitzpatrick, J.E.: Fungal Infections - Update 1984. Presented: Aspen Skin Seminar, Aspen, CO, July 1984.

Fitzpatrick, J.E.: Superficial Cutaneous Fungal Infections. Presented: 31st Annual Family Practice Seminar, Estes Park, CO, 15 June 1984.

Fitzpatrick, J.E.: Toilet Seats and Spirochetes. Presented: Aspen Skin Seminar, Aspen, CO, July 1984.

Grimwood, R.E., Johnson, C.A., Kramer, L.C., Mercill, D.B. and Huff, J.C.: Heterotransplantation of Human Basal Cell Epitheliomas in Nude Mice. Presented: SID Meeting, Washington, D.C., May 1984. (C).

Melette, J.R.: Practical Office Surgery I. Presented: Aspen Winter Skin Seminar, Aspen, CO, February 1984.

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Melette, J.R.: Treatment of BCC, SCC Cancers. Presented: Aspen Winter Skin Seminar, Aspen, CO, February 1984.

Hematology-Oncology Service

Howard, J.E.: A Microtiter-Enzyme-Linked Immunosorbent Assay (ELISA) for Quantitation of Platelet Bindable IgG (PBIgG). Presented: Fourth Annual Concepts in Hematology and Medical Oncology, Madigan Army Medical Center, Tacoma, Washington, 7 February 1984. (C).

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Iyengar, V.G.: Inhibitory Effects of Serum from Burn Patients on Colony Stimulating Factor (CSF) Production by Normal Monocytes. Presented: Fourth Annual Current Concepts in Hematology and Medical Oncology, Madigan Army Medical Center, Tacoma, Washington, 8 February 1984. (C).

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Zaloznik, A.J.: Mediastinal CT Scanning in Staging of Bronchogenic Carcinoma. Presented: 36th Annual Carl W. Tempel Symposium on Pulmonary Disease and Allergy-Immunology, Fitzsimons Army Meidcal Center, 24 January 1984.

Zaloznik, A.J.: Progress in Chemotherapy. Presented: Cancer Update 1984 sponsosred by American Cancer Society, 7 April 1984.

Zaloznik, A.J.: New Theories of Tumor Invasion and Metastasis. Presented: 38th Annual Rocky Mountain Cancer Conference, 9 August 1984.

Pulmonary Disease Service

Hendrix, C.: Bronchoalveolar Lavage Analysis in Sarcoidosis. Presented: 36th Annual Carl Tempel Symposium, Denver, CO, January 1984. (C).

Hendrix, C.: Bronchoalveolar Lavage in Analysis in Sarcoidosis. Presented: American College of Physicians Associates Meeting, Denver, CO, March 1984. (C).

Schlachter, M.D.: Lung Mechanics During HIgh Frequency Jet Ventilation Determined with Body Plethysmography in Mongrel Dogs. Presented: 36th Annual Carl Tempel Pulmonary Symposium, Denver, CO, January 1984. (C).

Schlachter, M.D.: Plethysmographic Determination of Lung Mechanics During High Frequency Jet Ventilation with CPAP. Presented: International Symposium on HIgh Frequency Ventilation, New York City, N.Y., November 1983. (C).

Wolfe, G.K.: Transbronchial Needle Aspiration - FAMC Experience. Presented: 36th Annual Carl Tempel Symposium, Denver, Co., January 1984. (C).

Wolfe, G.K.: Transbronchial Needle Aspiration in the Staging of Lung Cancer. Presented: American College of Physicians Meeting, Denver, CO., March 1984. (C).

(C) Direct result of approved registered protocol.

Rheumatology Service

Andersen P., West, S., Claypool, R., Odell, J., Kotzin, B. and Via, C.: Pulse Methotrexate Therapy for Rheumatoid Arthritis: A Double-Blind Crossover Study. Presented: National ARA Meeting, Minneapolis, Minnesota, June 1984. (C).

West, S. and Andersen, P.: Usefulness of Immunologic Tests of the CSF in the Diagnosis of CNS Lupus. Presented: National ARA Meeting, Minneapolis, Minnesota, June 1984. (C).

DEPARTMENT OF CLINICAL INVESTIGATION

Engelkirk, P.G., Paine, D.D., Purdon, A., Frye, L.P., Brady, W.K., Mahood, J.D. and Borchardt, K.A.: Evaluation of Plastic-Envelope-Microbiology (PEM) Technology for Rapid Diagnosis of Candida albicans and Trichomonas vaginalis Vaginitis. Presented: Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Las Vegas, Nevada, October 1983. (C).

Engelkirk, P.G.: Of Eosinophils, Mast Cells, and Parasites. Presented: Rocky Mountain Branch of the American Society for Microbiology. Presented: Summer Symposium on Host-Microbe Interactions, Pingree Park, Colorado, August 1984. (C).

Koester, S.K., Engelkirk, P.G., Paine, D.D., Wuerz, D.J. and Rothlauf, M.V.: Influence of Anti-Giardia Antibody, Heat-Labile Serum Components, and Sensitized Host Cells on Short-Term in Vitro Interactions Between G. lamblia Trophozoites and Rat Peritoneal Leukocytes. Presented: Annual Meeting of the American Society for Microbiology, St. Louis, Missouri, March 1984. (C).

Koester, S.K. and Engelkirk, P.G.: Glass Cover Slip Technique for Studying in Vitro Interactions Between Giardia Trophozoites and Host Leukocytes by TEM, SEM, and Light Microscopy. Presented: Rocky Mountain Branch of the American Society for Microbiology, Summer Symposium on Host-Microbe Interactions, Pingree Park, Colorado, August 1984. (C).

McNally, P., Herrera, L., Engelkirk, P. and Brewer, T.: Clinical Findings and the Immunofluorescent Antibody (IFA) Test in Patients with Giardiasis. Presented: William Beaumont Gastrointestinal Symposium, El Paso, Texas, March 1984. (C).

DEPARTMENT OF NURSING

Corcoran, D.K.: Nursing Role in Supporting Patients Who Have Experienced a Near-Death Experience. Presented: Fitzsimons Army Medical Center, Aurora, CO. May 19, 1984.

(C) Pilot study in approved registered protocol.

PRESENTATIONS FOR FY 84 Annual Progress Report Proto No. 74/110

SERVICE Endocrine DEPARTMENT Medicine

(1) Hofeldt, F.D.: Reactive Hypoglycemia: Update 1980. Presented: Endocrine Grand Rounds, University of Colorado Health Sciences Center, Denver, CO, 16 January 1980.

(2) Sanders, L.R.: Reactive Hypoglycemia. Presented: Grand Rounds, University of Colorado Health Sciences Center, Denver, CO, 13 March 1979.

(3) Sanders, L.R.: Reactive Hypoglycemia. Presented: Medical Grand Rounds, Denver General Hospital, Denver, CO, 15 March 1979.

(4) Sanders, L.R.: Reactive Hypoglycemia. Presented: Endocrine Grand Rounds, University of Colorado Health Sciences Center, Denver, CO, 11 April 1979.

(5) Hofeldt, F.D.: Hypoglycemia. Grand Rounds, Delgado Amphitheater, Tulane Medical School Charity Hospital, New Orleans, LA, 28 April 1982.

(6) Hofeldt, F.D. and Scarlett, J.A.: Reactive Hypoglycemia. Presented: Endocrine Grand Rounds, University of Colorado Health Sciences Center, Denver, CO, March 1982.

PUBLICATIONS for FY 84 Annual Progress Report Proto No. 74/110

SERVICE Endocrine DEPARTMENT Medicine

(1) Abrams, R., Hofeldt, F.D., Adler, R., O'Barr, T.P., and Morse, P.: Late Reactive Hypoglycemia in Hypothyroidism. (Accepted for publication in American Journal of the Medical Sciences.)

(2) Hofeldt, F.D.: Transitional Low Blood Glucose States. Rocky Mountain Medical Journal 76:30, 1979.

(3) McCowen, K.D., Adler, R.A., O'Barr, T.P., and Hofeldt, F.D.: Clinical Implications of Flat Oral Glucose Tolerance Test. Military Medicine 144:177, 1979.

(4) Charles, M.A., Hofeldt, F.D., Dodson, L.E., Shackelford, A., Waldeck, N., Bunker, D., Coggins, J.T., and Eichner, H.: Comparison of Glucose Tolerance Tests and Mixed Meals in Patients with Idiopathic Reactive Hypoglycemia: Absence of Hypoglycemia After Mixed Meals. Diabetes 30:465, 1981.

(5) Sanders, L.R., Hofeldt, F.D., Kirk, M., and Levin, J.: Refined Carhohydrate as a Contributing Factor in Reactive Hypoglycemia. Southern Medical Journal 75:1072, 1982.

(6) Crapo, P.A., Scarlett, J.A., Kolterman, O., Sanders, L., Hofeldt, F.D., and Olefsky, J.: The Effects of Oral Fructose, Sucrose and Glucose in Subjects With Reactive Hypoglycemia. Diabetes Care 5:512, 1982.

(7) Sanders, L.R., Hofeldt, F.D., Kirk, M.C., and Levin, J.: Refined Carbohydrate as a Contributing Factor in Reactive Hypoglycemia. Southern Medical Journal 75:1072-1075, 1982.

(16) Continued

prolactins and cortisols are sampled and values are determined by a sensitive radioimmunoassay. Blood glucoses are assessed by the Ames Reflectance Meter immediately after sampling. The procedure is designed to provide a minimum of patient inconvenience in the performance of these well standardized procedures. Many normal individuals experience a low blood sugar state sometime after glucose administration, the significance of a low blood glucose state is observed by recording appropriate adrenergic symptoms at the nadir of the glucose and determining if there is a counter hormonal responsiveness to defend the stress of a low blood glucose state. This approach allows strict definition of bona fide reactive hypoglycemia, and clearly distinguishes it from the benign low blood glucose states.

(17) Progress:

This study continues to be an active endocrine protocol with recruitment of new patients for evaluation and study. Several publications elucidating the unusual features of this disorder have resulted from this study. During the last year, patients have been entered onto a computer for ease in data management and retrieval of information. Efforts are now being made to organize the data in the preparation for commencing several written reports on hypoglycemia in general, and some specific aspects that have studied in the present ongoing protocol.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 74/110 (3) Status: Ongoing

(4) Title: Reactive Hypoglycemia: An Analysis of Glucose-Insulin-Glucagon Interrelationships and Counter Hormonal Regulatory Factors

(5) Start Date: FY71	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Michael Bornemann, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Endocrine	(10) Assoc Investigators: Fred D. Hofeldt, M.D. T. P. O'Barr, Ph.D., DAC Annelie Shackelford, MT, DAC Gerald S. Kidd, MD, LTC, MC
(11) Key Words: reactive hypoglycemia glucose tolerance counter-regulatory hormones	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 10/83 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 18

d. Total Number of Subjects Enrolled to Date: 384

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None.

(15) Study Objective:

The objectives of the hypoglycemic study is to continue to investigate in our clinic population the glucose-insulin-glucagon and prolactin interrelationships and the response of counter-regulatory hormones to hypoglycemic stress. This project is a continuation of the previous project initiated in 1969 at the University of California Medical Center, Moffatt Hospital, San Francisco, CA.

(16) Technical Approach:

The clinical research protocol involves evaluation of control subjects and hypoglycemic patients to assess the interrelationships of beta cell and alpha cell responsiveness to oral and intravenous glucose administration. Based upon findings in controls and patients with disease states, a classification system has been proposed. The data have allowed for an understanding of the basic pathophysiology of reactive hypoglycemia disorders. The clinical studies are being conducted in the Department of Medicine, Endocrine Clinic, with the assistance of an assigned GS-5 Medical Technician to perform blood sampling and to assist during the testing. During the glucose tolerance test, the patient has an indwelling catheter for frequent sampling of blood glucose, and is continually monitored by a cardiac monitor system and blood sampling. After glucose administration, blood insulins, glucagons, growth hormones,

MEDICINE

DETAIL SUMMARY SHEETS

EXPLANATION of ANNUAL PROGRESS REPORT DETAIL SHEETS

(1) DATE: Fiscal Year ending date.

(2) PROTOCOL NO: FAMC Work Unit Number of the study.

(3) STATUS: Indicates if the study is Ongoing, Completed, or Terminated.

(4) TITLE: Project title of the study.

(5) START DATE: The date the study started.

(6) ESTIMATED COMPLETION DATE: The projected completion date of the study.

(7) PRINCIPAL INVESTIGATOR(s): List of all Principal Investigator(s) involved in the study.

(8) FACILITY: Fitzsimons Army Medical Center.

(9) DEPARTMENT/SECTION: Department or Service the protocol originated from.

(10) ASSOCIATE INVESTIGATOR(s): List of all Associate Investigator(s) involved in the study.

(11) KEY WORDS: Key words pertaining to the particular area of research involved in the study.

(12) ACCUMULATIVE MEDCASE COST: See Unit Summary Sheet - Funding.

(13) ESTIMATED ACCUMULATIVE OMA COST: See Unit Summary Sheet - Funding

(14) PERIODIC REVIEW RESULTS: Date of the continuing review by the Institutional Review Committee.

(15) STUDY OBJECTIVE: A summary of objectives to be accomplished during the study.

(16) TECHNICAL APPROACH: A brief summary of the technical approach to be taken during the study.

(17) PROGRESS: A summary of prior and current progress since inception of the study.

The Continuation Sheets are used as extensions for (1) - (17) and as an accumulative listing for Publications and Presentations that are a direct result from the study.

The Detail Sheets were submitted in final form by the Principal Investigators and have not been edited.

Hendrix, W.H., Rodriquez, A.R. and Presley, A.: Stress Effect on Organizational Outcomes and Prediction of CAD Risk. Presented: 92nd Annual American Psychological Association Convention, Toronto, Canada, August 1984.

Rodriquez, A.R., Iverson, D.C., Hendrix, W.H. and Presley, A.: An Employee Directed Wellness Project: Early Findings from the OCHAMPUS Health Promotion Program. Presented: American Public Health Association Meeting, Dallas, Texas, November 1983.

MEDDAC

Wallace, L.S.: Stabilization of Hemoglobins and Hematocrits in Females Travelling from a Lower to Higher Altitude. Presented: Nursing Research Symposium, Washington, D.C., 10-14 September 1984.

(C) Direct result of approved registered protocol.

Vordermark, J.S.: Transureteroureterostomy: A Review of its Use in Modern Pediatric Urology. Presented: British Association Urologic Surgeons Meeting, Dublin, Ireland, June 1984.

Vordermark, J.S.: Pelvic Fracture Strictures: A Review of 100 Consecutive Cases. Presented: British Association Urologic Surgeons Meeting, Dublin, Ireland, June 1984.

DEPARTMENT OF RADIOLOGY

Perry, M., Blue, P., Kindig, N. and Ghaed, N.: Pressure Wave Form Correlation with Xenon Wash-Out Time in a Physical Model of High Frequency Ventilation. Presented: Sloan-Kettering Cancer Center, November 1983. (C).

Tucker, A.S. and Crimmins, L.: Exhibit: A Case Report of Multiple Esophageal Duplications. Presented: European Pediatric Society, Florence, Italy, April 1984.

Tucker, A.S. and Crimmins, L.: Exhibit: A Case Report of Multiple Esophageal Duplications. Presented: Rocky Mountain Radiology Scoiety, Denver, Colorado, August 1984.

DEPARTMENT OF PRIMARY CARE AND COMMUNITY MEDICINE

Bethlenfalvay, N.C., Hadnagy,m C.S. and Heimpel, H.: A New Type of Congenital Dyserythropoietic Anemia: Evidence for Delayed Denucleation. Presented: 27th Annual Meeting of the Hungary Society of Hematology, Szeged, Hungary, August 1984.

FAMC TENANT

Hendrix, W.H. and Rodriquez, A.R.: Effects of Stress on Individual Productivity, Absenteeism, and Wellness. Presented: Ninth Biennial Psychology in the DOD Symposium, USAFA, Colorado, April 1984. (C).

Hendrix, W.H., Rodriquez, A.R. and Presley, A.: Effects of Stress and Exercise on Employee Health. Presented: Fifth Annual Meeting of the Society of Behavioral Medicine, Philadelphia, PA, May 1984. (C).

Hendrix, W.H., Rodriquez, A.R. and Presley, A.: Job and Personal Factors Related to Job Stress and Risk of Developing Coronary Artery Disease. Presented: American Industrial Hygiene Conference, Detroit, Michigan, May 1984. (C).

(C) Direct result of approved registered protocol.

Scharfenaker, S.K.: A Reactive Language Approach to Apraxia Therapy with Children. Presented: Colorado Speech-Language-Hearing Association Annual Convention, Copper Mountain, April 1984.

Urology Service

Fauver, H.E.: Paratesticular Tumors: Presented: Kimbrough Urological Seminar, San Francisco, CA, November 1983.

Fauver, H.E.: Benign Testis Masses. Presented: Kimbrough Urological Seminar, San Francisco, CA, November 1983.

Fauver, H.E.: Endometrial Cancer of Prostate. Presented: AUA Meeting, New Orleans, LA, May 1984.

Vordermark, J.S.: Complex Hypospadias. Presented: Seminar on Plastic Surgery, sponsored by the British Association of Plastic Surgeons, Birmingham, England, April 1984.

Vordermark, J.S.: The Acute Scrotum: Diagnosis and Mangement. Presented: Seminar on Urological Emergencies, Institute of Urology, London, England, May 1984.

Vordermark, J.S.: Principles of Plastic and Reconstructive Urological Surgery. Presented: Seminar on Reconstructive Urological Surgery, Institute of Urology, London, England, April 1984.

Vordermark, J.S.: The Hypospadias Cripple. Presented: Seminar on Reconstructive Urological Surgery, Institute of Urology, London, England, April 1984.

Vordermark, J.S.: Hypospadias and Epispadias and Extrophy - The State of the Art. Presented: West Middlesex Hospital, London, England. Presented: Regional Center for Plastic and Reconstructive Surgery, Mount Vernon Hospital, Northwood, Middlesex, England.

Vordermark, J.S.: Epididymitis: Ancillary Diagnostic Techniques. Presented: Queen Elizabeth Royal Army Medical Hospital, Woolich Arsenal, England, June 1984.

Vordermark, J.S. and Jones, B.M.: Approaches to Block Dissection of the Inguinal Lymph Nodes. Presented: British Association of Plastic Surgeons, London, England, November 1983.

(C) Direct result of approved registered protocol.

Loth, T.S. and Eversmann, W.W. Jr.: Treatment of Chemotherapeutic Agent Extravasations: A Comparative Study. Presented: Barnard Lectureship presented to the Rocky Mountain Chapter of the Western Orthopaedic Society, Denver, CO., December 1983. (C).

Otolaryngology Service

Blakeslee, D.B., Becker, G.D., Simpson, G.T., Patten, D.H. and Sprengelmeyer, J.: Lymphoscintography of the Neck after Tumor Injection. Presented: Research Forum, Anaheim, CA., 22 October 1983.

Hasbrouck, J.M., Doherty, J., Mehlmann, M.A., Nelson, R., Randle, B. and Whitaker, R.: Intensive Stuttering Therapy in a Public School Setting. Presented: Colorado Speech-Language-Hearing Association Annual Convention, Copper Mountain, CO., April 1984. (C).

Hasbrouck, J.M. and Lowry-Romero, M.F.: An Intensive Therapy Approach to Eliminating Stuttering and Maintaining Fluency. Presented: American Speech-Language-Hearing Association Annual Convention, Cincinnati, OH., November 1983. (C).

Hasbrouck, J.M. and Lowry-Romero, M.F.: An Intensive Therapy Approach to Eliminating Stuttering and Maintaining Fluency. Presented: Colorado Speech-Language-Hearing Association Annual Convention, Copper Mountain, CO., April 1984. (C).

Lowry-Romero, M.F.: Care and Treatment of the Professional Voice. Presented: Colorado Speech-Language-Hearing Association Annual Convention, Copper Mountain, CO., April 1984.

McMahan, D.A.: A Hearing Impaired Child's Learning Style vs. Educator's Teaching Preferences - A Case Study. Presented: Colorado Speech-Language-Hearing Association Annual Convention, Copper Mountain, CO., April 1984.

McMahan, D.A., Hasbrouck, J.M., Scharfenaker, S.K. and Porter, M.: Let's Look at Children's Learning Styles, Not Educators' Teaching Preferences. Presented: A.G. Bell Association for the Deaf International Convention, Portland, OR., June 1984.

Prescott, T. and Lowry-Romero, M.F.: Alaryngeal Voice: State of the Art. Presented: Colorado Speech-Language-Hearing Association Annual Convention, Copper Mountain, CO., April 1984.

(C) Direct result of approved registered protocol.

Merenstein, G.B. and Kirk, E.P.: A View to the Future: What Next in Transport? Regionalization? Presented: Maternal Transport, Bend, OR., May 1984.

Merenstein, G.B.: Neonatal Manpower. Presented: Military Perinatal Research, Aspen, CO., July 1984.

Murphy, M.G.: Application of a Bayesian Drug Dosing Program in Newborns. Presented: Uniformed Services Pediatric Seminar, Reno, NV, March 1984.

Murphy, M.G.: Revisions of Gentamycin Therapy with a Bayesian Computer Program. Presented: Mead Johnson Perinatal Research Meeting, Aspen, CO., July 1984. (C).

DEPARTMENT OF SURGERY

General Surgery Service

Allen, J.J. and Clark, J.R.: Cecal Volvulus: Report of 10 Cases and a Review of the Literature. Presented: Gary Wratten Surgical Symposium/Workshop, Walter Reed Army Medical Center, Washington, D.C., April 1984.

Orthopedic Service

Houseworth, S.W., Curl, W.W., Smith, C.K. and Eilert, R.E.: Use of the Arthroscope to Evaluate Immediate and Delayed Anterior Cruciate Ligament Reconstruction: An Experimental Study in the Dog. Presented: Yearly Barnard Seminar with the University of Colorado Orthopedic Surgery Program, 5 December 1984. (C).

Houseworth, S.W., Mauro, V.J. and Mellon, B.S.: The Intercondylar Notch in Acute Tears of the Anterior Cruciate Ligament: A Computer Graphics Study. Presented: Anterior Cruciate Ligament Study Group. Steamboat Springs, CO., March 16-18, 1984. (C).

Loth, T.S.: Minimal Surgical Debridement of Cehmotherapeutic Agent Extravasations. Presented: Mid-Central States Orthopedic Society, Lake of Ozarks, MO., June 1, 1984. (C).

Loth, T.S.: Minimal Surgical Debridement of Chemotherapeutic Agent Extravasations. Presented: Denver Children's Hospsital Orthopedic Day, Denver, CO., 27 April 1984. (C).

Loth, T. and Eversmann, W.W. Jr.: Treatment of Chemotherapeutic Agent Extravasations: A Comparative Study. Presented: American Society for Surgery of the Hand Meeting, Atlanta, GA., 6 February 1984. (C).

(C) Direct result of approved registered protocol.

Merenstein, G.B. and Kirk, E.P.: A View to the Future: What Next in Transport? Regionalization? Presented: Maternal Transport, Bend, OR., May 1984.

Merenstein, G.B.: Neonatal Manpower. Presented: Military Perinatal Research, Aspen, CO., July 1984.

Murphy, M.C.: Application of a Bayesian Drug Dosing Program in Newborns. Presented: Uniformed Services Pediatric Seminar, Reno, NV, March 1984.

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Loth, T.S.: Minimal Surgical Debridement of Chemotherapeutic Agent Extravasations. Presented: Mid-Central States Orthopedic Society, Lake of Ozarks, MO., June 1, 1984. (C).

Loth, T.S.: Minimal Surgical Debridement of Chemotherapeutic Agent Extravasations. Presented: Denver Children's Hospsital Orthopedic Day, Denver, CO., 27 April 1984. (C).

Loth, T. and Eversmann, W.W. Jr.: Treatment of Chemotherapeutic Agent Extravasations: A Comparative Study. Presented: American Society for Surgery of the Hand Meeting, Atlanta, GA., 6 February 1984. (C).

(C) Direct result of approved registered protocol.

DEPARTMENT OF PATHOLOGY

Stocker, J.T.: Congenital Lung Disease. Presented: Armed Forces Institute of Pathology Course on Pediatric Pathology, Washington, D.C., 27 October 1983.

Stocker, J.T.: Pulmonary Sequestration. Presented: Webb Waring Pediatric Pulmonary Lecture Series, Denver, CO., 20 January 1984.

Stocker, J.T.: Interlobar Sequestration; an Acquired Disorder. Presented: Symposium on Pulmonary Medicine, FAMC, 24 January 1984.

Stocker, J.T.: Bronchopulmonary Dysplasia. Presented: Society for Pediatric Pathology, San Francisco, CA., 10 March 1984.

Stocker, J.T.: Pediatric Liver Tumors, Polyposis Syndrome, Congenital Lung Disease. Presented: Aspen Conference on Pediatric Disease, Aspen, CO., 6-10 August 1984.

DEPARTMENT OF PEDIATRICS

Berkenbaugh, J.T.: Polycythemia/Hyperviscosity: Some Unanswered Questions. Presented: Military Perinatal Research Meeting, Aspen, CO., July 1984.

Portman, R.J., Cole, J.W., Perlman, J.M., Lim, Y. and Robson, A.M.: Tubular Dysfunction in Infants with Meconium Stained Amniotic Fluid Diagnosis Using B2 Microglobulins. Presented: Society for Pediatric Research, San F-ancisco, CA., May 1984. (C).

Portman, R.J.: Tubular Dysfunction in Neonates Diagnosed by the Urinary Concentration of B2 Microglobulins. Presented: Aspen Conference on Military Perinatal Research, Aspen, CO., August 1984. (C).

Sanders, J.M.: Adolescent Medicine in the Military, Present and Future Issues. Presented: 19th Annual Uniformed Services Pediatric Seminar, Reno, NV, March 1984.

Sanders, J.M.: General Approach to the Adolescent Patient: Substance Abuse. Presented: 62nd Annual Meeting of the Texas Pediatric Society, Dallas, TX, September 1984.

Merenstein, G.B.: Maternal Transport: A Military Perspective. Presented: Maternal Transport, Bend, OR., May 1984.

(C) Direct result of approved registered protocol.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 78/102 (3) Status: terminated

(4) Title: The development of specific and cross sensitivity in the tracheal tissue of guinea pigs treated with isoproterenol and aminophylline

(5) Start Date: 1978	(6) Est Compl Date: 1984
(7) Principal Investigator: W.R. Tipton, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Med/Allergy	(10) Assoc Investigators: none
(11) Key Words: subsensitivity beta agonists guinea pig trachea	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

NA

(15) Study Objective: This study is designed to measure the development of the subsensitivity to two drugs, isoproterenol and theophylline, by examining both their dilating response on histamine contracted tracheal tissue and ability to increase levels of cyclic-AMP in tracheal tissue and parenchymal lung tissue.

(16) Technical Approach: Guinea pig tracheal and peripheral lung strips will be analyzed for cyclic nucleotide levels, metabolites of arachodonic acid and physiologic response to various medicators employing a continuous flow tissue bath system. The equipment for this study is presently available at Fitzsimons Army Medical Center.

(17) Progress: Terminated.

Publications: Tipton WR, Nelson HS, Souhrada JF, Morris, HG, Jacobson KW: Dynamics of isoproterenol subsensitivity in guinea pig airway smooth muscle. Lung 159:199; 1981.

PRESENTATIONS FOR FY 84 Annual Progress Report Proto No. 78/102

SERVICE Allergy DEPARTMENT Medicine

1. Tipton WR: Dynamics and mechanism of guinea pig trachea subsensitivity to isoproterenol. Presented: 31st Annual Pulmonary Disease Symposium, FAMC, Sep 78.

2. Tipton WR: Dynamics and mechanism of guinea pig trachea subsensitivity to isoproterenol. Presented: American Thoracic Society, Las Vegas, NV, May 79.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 78/114 (3) Status: Ongoing

(4) Title: In vitro effect of minoxidil on collagen production by normal and scleroderma fibroblasts. (Previously titled: "The use of minoxidil in treating progressive systemic scleroderma."

(5) Start Date: Jan 1979	(6) Est Compl Date: Oct 84
(7) Principal Investigator: James E. Fitzpatrick MD Maj, MC	(8) Facility: FAMC
(9) Dept/Svc: DOM/Dermatology	(10) Assoc Investigators: Thomas P. O'Barr PhD, DAC Ellen Swanson MS, DAC Don Mercill, DAC
(11) Key Words: scleroderma/minoxidil/ fibroblasts/collagen	

(12) Accumulative MEDCASE:* N/A (13) Est Accum OMA Cost:* N/A
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period: N/A
d. Total Number of Subjects Enrolled to Date: N/A
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective: To determine if minoxidil inhibits the in-vitro production of collagen by normal and scleroderma fibroblasts.

(16) Technical approach: Fibroblast cell lines have been established from human dermis obtained from normal and scleroderma patients. The fibroblasts are then incubated in the presence of various concentrations of minoxidil. The production of collagen will be measured by uptake of radioactive proline.

(17) Progress: The in vivo portion of the protocol was completed as of 30 September 1982.

The in-vitro portion of the portocol is almost complete. The incubation and sampling portion of the protocol is finished. We are currently in the process of analyzing the samples and if all goes well the protocol will be finished in 2 to 4 weeks.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 78/123 (3) Status: ongoing

(4) Title: A Comparison of the Zimmerer and Dubois Techniques of Airway Resistance Measurements by Body Plethysmography

(5) Start Date: 1979	(6) Est Compl Date: indefinite
(7) Principal Investigator: Michael Perry, COL MC	(8) Facility: FAMC
(9) Dept/Svc:Medicine/Pulmonary	(10) Assoc Investigators: Robert W. Zimmere, Ph.D. Robert J. Browning, B.S. DAC
(11) Key Words: Alveolar Pressure Airway resistance body plethysmography	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 7

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A

(15) Study Objective: To compare a clinically untried measurement of airway resistance with a standard technique.

(16) Technical Approach: Forced expiratory maneuvers are performed with the subject seated in a constant volume body plethysmograph, while plethysmograph pressure and airflow are monitored with a DEC computer. With this information and the previously determined FRC of the patient, alveolar pressure is calculated throughout the expiratory maneuver. Pressure/flow relationships are then related to the patient's maximal expiratory flow volume loop.

(17) Progress: This protocol had been inactive during the past FY due to extensive changes and modifications of our equipment, including a new computer, new plethysmograph and recording system and the ongoing rewrite of our entire computer program.

PUBLICATIONS for FY 84 Annual Progress Report Proto No. 78/123

SERVICE Pulmonary DEPARTMENT Medicine

1). Perry, M.E., Zimmerer, R.W., Browning, R.J.: Non-Invasive Alveolar Pressure/Flow Pattern Determination by Computerized Plethysmography (Abstract) Symposium on Computers in Critical Care in Pulmonary Medicine, Page 47, June 1980.

2). Perry, M.E., Zimmerer, R.W., Nelson, R.A., Browing, R.J., Non-Invasive Determination of Alveolar Pressure-Flow Relationship (Abstract) American Review of Respiratory Disease, Volume 121, Page 389, April 1980.

3). Zimmerer, R.W., Perry, M.E., Browning, R.J: Expiratory Pressure/Flow Assessment by Plethysmography (Abstract) AAMI 15th Annual Meeting, Page 246, April 1980.

4). Perry, M.E., Zimmerer, R.W., Browning, R.J: "Non-Invasive Alveolar Pressure/Flow Pattern Determinations by computerized Plethysmography", Computers in Critical Care and Pulmonary Medicine, Volume 2, PP 75-77 Plenum Press, 1982.

PRESENTATIONS:

1) Perry, M.E., Zimmerer, R.W., Browning, R.J.: Non-Invasive Alveolar Pressure/Flow Pattern Determination by Computerized Plethysmography, presented at the Annual Computers in Critical Care and Pulmonary Medicine, Lund, Sweden, June 3-6, 1980.

2) Zimmerer, R.W., Perry, M.E., Browning, R.J.: Expiratory Pressure/Flow Assessment by Plethysmography, presented at the AAMI 15th Annual Meeting San Francisco, April 13-17, 1980.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#78/124 (3) Status: ongoing

(4) Title: A self-consistent Method of Single-Breath DLCO measurement

(5) Start Date: Sept 1978	(6) Est Compl Date: indefinite
(7) Principal Investigator: Michael E. Perry, COL MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Pulmonary	(10) Assoc Investigators: Neal B. Kindig, Ph.D Robert J. Browning, P.S.
(11) Key Words: Single Breath Diffusion Alveolar Gas' Breathing Patterns	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 5

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A

(15) Study Objective: To Experimentally comfirm a proposed new method of DLCO Measurement.

(16) Technical Approach: Data will be sampled during the single breath DLCO determination at various breath-holding times at various exhaled lung volumes. Data will be analyzed online by computer which will correct for volume averaging and effective breathi-holding time. If the theoretical approach as outlined in the original protocol is self-consistent, the calculated diffusion capacity should remain constant regardless of breathing pattern of gas collection timing.

(17) Progress: This protocol remains inactive this FY due to other commitments within the service.

PRESENTATIONS FOR FY 84 Annual Progress Report Proto No. 78/124

SERVICE Pulmonary DEPARTMENT Medicine

1). Zimmerer, R.W.: Simulated Diffusion Testing. Presented: 32nd Annual Pulmonary Symposium, FAMC, Aurora, CO, September 1979.

2). Browning, R.J., Kindig, N.B., Perry, M.E., "Computer Control Aspects of a Single Breath DLCO Station." Presented at the Nineteenth International Instrument Society of America Biomedical Sciences Instrumentation Symposium, Denver, CO, April, 1982.

3). Kindig, N.B., Perry, M.E., Browning, R.J., "Single Breath DLCO: Inspiratory Timing and Volume Averaging". Presented at the Annual FASEB Meeting, New Orleans, April, 1982.

4). Kindig, N.B., "Single Breath DLCO: Improved Time and Volume Measurement". Persented at the Annual Carl W. Tempel Pulmonary Symposium, Denver, CO, Jan, 1982.

5). Perry, M.E., "Mechanism of Carbon Monoxide Effect on Oxyhemoglobin Dissociation". Persented at the Annual Carl W. Tempel Pulmonary Symposium, Denver, CO, Jan, 1982.

PUBLICATIONS:

1). Kindig, N.B., Hazlett, D.R., Filley, G.F.: "Timing and Volume Averaging in Single Breath DLCO Measurement". The Physiologist, 21:64, 1978

2). Browning, R.J., Kindig, N.B., Perry, M.E., "Computer Control Aspects of a Single Breath DLCO Station." Biomedical Sciences Instrumentation, Volume 18, April, 1982.

3). Kindig, N.B., Perry, M.E., Browning, R.J., "Single Breath DLCO: Inspiratory Timing and Volume Averaging (ABS) Federation Proceedings, Volume 41, Mar, 1982.

PRESENTATIONS FOR FY 84 Annual Progress Report Proto No. 79/105

SERVICE Pulmonary DEPARTMENT Medicine

1). Kindig, N.B.: DLCO correction using PaCO back pressure predicted from venous blood. Presented: Carl E. Tempel Pulmonary Symposium, Denver, CO, January, 1981.

2). Perry, M.E.: Simplified room air (A-a)O_2 calculation. Presented: Carl E. Tempel Pulmonary Symposium, Denver, Colorado, January, 1981.

PUBLICATIONS:

1). Perry, M.E., Browning, R.J., Kindig, N.B., "The Abbreviated Alveolar Air Equation Revisited, Chest, Volume 80, pp 763-764, December, 1981.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 79/109 (3) Status: Terminated

(4) Title: Control of Nausea and Vomiting with Delta-9-tetrahydrocannabinol (THC) Combined with Standard Antiemetics (A Phase II Study)

(5) Start Date: June 1980	(6) Est Compl Date: July 1984
(7) Principal Investigator: Nicholas J. DiBella, M.D.,COL,MC	(8) Facility: FAMC
(9) Dept/Svc Medicine/Hema/Oncology	(10) Assoc Investigators: Arlene J. Zaloznik, M.D., MAJ, MC
(11) Key Words: Chemotherapy, nausea and vomiting control	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Sep 83 b. Review Results: Continued

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 54

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

1) To determine if THC has a useful antiemetic effect when added to standard antiemetic regimen.
2) To determine if the antiemetic effect is additive or potentiating.
3) To determine if THC reduces nausea and vomiting in those patients who do not respond to standard antiemetics.

(16) Technical Approach:
Clinical study

(17) This protocol was terminated by the principal investigator. All remaining THC was returned to the NCI.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 79/112 (3) Status: Ongoing

(4) Title: Use of Sodium Salt of Allopurinol to Control Hyperuricemia in Patients with No Therapeutic Alternative. A Pilot Study.

(5) Start Date: March 1980	(6) Est Compl Date: 1985
(7) Principal Investigator: Arlene J. Zaloznik, M.D.,MAJ,MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Hema-Oncology	(10) Assoc Investigators: Kenneth Beougher, MAJ, MSC
(11) Key Words: Hyperuricemia, Allopurinol	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 30 Sep 83 b. Review Results: continued

c. Number of Subjects Enrolled During Reporting Period: None

d. Total Number of Subjects Enrolled to Date: Three

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective:

To determine the effect of a parenteral form of allopurinol to control hyperuricemia when the patient is unable to take the tablet form (commercially available).

(16) Technical Approach:

Clinical Study

(17) Progress:

No new patients have been entered on this study but it should be kept open since the medication is not commercially available and it may be needed in the patient who requires antitumor therapy but is unable to take oral allopurinol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 80/104 (3) Status: Terminated

(4) Title: Etoposide Combined with Cyclophosphamide Plus Vincristine Compared to Both Doxorubicin Plus Cyclophosphamide Plus Vincristine in the Treatment of Small Cell Lung Cancer

(5) Start Date: 1980

(6) Est Compl Date: July 1984

(7) Principal Investigator:
Arlene J. Zaloznik,M.D.,MAJ,MC

(8) Facility: FAMC

(9) Dept/Svc Medicine/Hema-Oncology

(10) Assoc Investigators:
Nicholas J. DiBella, M.D., COL, MC

(11) Key Words:
Small cell
Oat cell
Chemotherapy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Sep 83 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective:

To assess the efficacy of Etoposide combined with other chemotherapy for the treatment of small cell lung cancer.

(16) Technical Approach: Clinical study.

(17) Progress: Etoposide has now become commercially available and is FDA approved. Bristol Laboratories have closed the protocol. No data is as yet available with results.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 80/115 (3) Status: Ongoing

(4) Title:

EVALUATION OF AMIODARONE FOR THE THERAPY OF CARDIAC ARRHYTHMIAS

(5) Start Date: 1980	(6) Est Compl Date: Indefinite
(7) Principal Investigator: RICHARD C. DAVIS, JR., MD, Ph.D. LTC, MC ASST CHIEF, CARDIOLOGY SERVICE	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words: Amiodarone Cardiac Arrhythmias	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 4 (thru Aug 84)

d. Total Number of Subjects Enrolled to Date: 10

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To control symptomatic cardiac arrhythmias which have not been responsive to the conventional and accepted forms of treatment or whose control is dependent upon the use of a drug which has been shown to be harmful to or in other ways not tolerated by the individual.

(16) Technical Approach: After patient selection, baseline laboratory results as outlined in the protocol will be obtained. After initiation of therapy, the patient will be followed regularly by the principal investigator with frequent Holter monitors to assess the efficacy of the drug and other laboratory tests and examinations to warn of potential toxicity.

(17) Progress: Four additional patients have been recruited. Four have shown a satisfactory response while one did not respond.

Publications and presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 80/117 (3) Status: on-going

(4) Title: Correlation of clinical signs and symptoms with assays of circulating immune complexes.

(5) Start Date: Oct 80	(6) Est Compl Date: 1984
(7) Principal Investigator: W.Ronald Tipton, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Allergy	(10) Assoc Investigators: V. Iyengar, MD, LTC, MC Jeneen Nelson
(11) Key words: immune complexes C1Q laboratory assays	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

NA

(15) Study Objective: The purpose of this study is to determine the relative sensitivity of several laboratory assays for immune complexes in patients with suspected immune complex disorders.

(16) Technical Approach: Patients in whom serum submitted for antinuclear antibodies will have a standard clinical evaluation and their serum will be examined by a standardized battery of four assays for the circulating immune complexes. Correlations will then be made to determine which of the assays best reflects clinical disease.

(17) Progress: Approximately 250 samples have been correlated with the chart review by Dr. Iyengar. Correlation coefficient statistics have indicated no significant correlation between the two parameters; however, further analysis is being done utilizing different clinical criteria.

PRESENTATIONS FOR FY 84 Annual Progress Report Proto No. 80/117

SERVICE Allergy DEPARTMENT Medicine

Iyengar V: This paper has been accepted for presentation at a Hematology-Oncology Meeting in San Francisco, Sep 84.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 81/117 (3) Status: Ongoing

(4) Title: The Role of Calcitonin in Osteoporosis

(5) Start Date: November 1982	(6) Est Compl Date: December 1984
(7) Principal Investigator: Michael T. McDermott, MD, MAJ,MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Endocrine	(10) Assoc Investigators: Gerald S. Kidd, MD, LTC, MC Peter Blue, MD, LTC, MC Nasser Ghaed, MD, COL, MC Fred D. Hofeldt, M.D.
(11) Key Words: osteoporosis calcitonin deficiency bone density	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Nov 82 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 60

d. Total Number of Subjects Enrolled to Date: 60

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None

(15) Study Objective:

The objectives of this study are to further investigate the role of calcitonin, or its deficiency, in the development of osteoporosis and to determine if thyroidectomized patients, who are calcitonin deficient, are at increased risk of developing osteoporosis.

(16) Technical Approach:

Four groups of individuals are studied with bone densitometry using the Norland apparatus. A control group of normals and a thyroid suppressed group of patients compared with a group of thyroidectomized patients who are therefore calcitonin deficient.

(17) Progress:

Sixty patient have had serial bone density measurements on two occasions; 40 patients have also had a third bone density measurement. The remainder of the patients are currently being scheduled for their third measurement. Pentagastrin infusions have not yet been done because of difficulty with the calctionin radioimmunoassay. Data from the first bone density measurements has already been published.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 81/116 (3) Status: Terminated

(4) Title: Hypertransfusion in Acute Leukemia

(5) Start Date: October 1981	(6) Est Compl Date: Unknown
(7) Principal Investigator: Arlene J. Zaloznik,M.D.,MAJ,MC	(8) Facility: FAMC
(9) Dept/Svc Medicine/Hema-Oncology	(10) Assoc Investigators: Nicholas J. DiBella, M.D., COL, MC
(11) Key Words: Hypertransfusion Acute Leukemia	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Sep 83 b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 19

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

No adverse drug reactions.

(15) Study Objective:

To determine the advantage of maintaining an elevated hematocrit during induction chemotherapy for acute leukemia vs the maintenance of an adequate hematocrit.

(16) Technical Approach:

Patients undergoing induction chemotherapy for acute leukemia are randomized into receiving packed red blood cells to maintain a hematocrit greater than 45% during induction vs those who receive packed red blood cells only if clinically indicated.

(17) Progress:

Although initially there appeared to be a trend in the hypertransfused group of the platelet count not dropping as low as the nontransfused group this apparent trend did not continue to be upheld. The study was terminated because it was felt by the principal investigator that it offered no significant benefit to those patients who were being hypertransfused.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 81-115 (3) Status: Ongoing

(4) Title: Comparison of Modalities for Treatment of SLE Nephritis

(5) Start Date: 1982	(6) Est Compl Date: 1986
(7) Principal Investigator: Sterling G West, MD, C, Rheumatology Svc, MAJ, MC; Peter A. Andersen, MD, AsstC, Rheumatology Svc, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators: Mark Nelson, MD, MAJ, MC
(11) Key Words: SLE, nephritis, steroids, Chlorambucil	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: June 1984 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: three
d. Total Number of Subjects Enrolled to Date: seven
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

One patient developed neutropenia

(15) Study Objective: a. To evaluate the efficacy and side effects of single daily dose corticosteroids versus split dose steroid therapy. b. Provide an alternative form of therapy in patients with SLE nephritis that have not responded to conventional steroids and to evaluate the patient's clinical and serologic response to therapy.

(16) Technical Approach: Patients with lupus nephritis are randomly assigned after informed consent to one of two modes of therapy--either split dose or single dose steroids. A variety of serologic parameters are monitored indicating a response to these medications. Patients who do not respond to this therapy are randomized to either receiving high-dose pulse steroids or Chlorambucil again on a random method. Again, serologic parameters are followed to indicate response to this therapy.

(17) Progress: During the past fiscal year there have been three patients at this institution who have fulfilled entry criteria for incorporation into the protocol. Review of the protocol with the other medical centers in the Army revealed, furthermore, that there has been a significant difficulty in enrolling additional patients. The rigid entry requirements which increase the power of this analysis limits the applicability of the protocol to some patients. It is expected that further evaluation of the status will be made during the next fiscal year.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 81/113 (3) Status: Terminated

(4) Title: Aminocaproic Acid for the Control of Hemorrhage in Thrombocytopenic Patients

(5) Start Date: May 1981	(6) Est Compl Date:
(7) Principal Investigator: Arlene J. Zaloznik,M.D.,MAJ,MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Hema-Oncology	(10) Assoc Investigators: Nicholas J. DiBella, M.D., COL, MC
(11) Key Words: Aminocaproic Acid Thrombocytopenia	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Sep 83 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective:
To determine the efficacy of 1) Prophylactic AMICAR compared with prophylactic platelet transfusions to prevent hemorrhage in thrombocytopenia patients; 2) AMICAR compared with platelet transfusions to control hemorrhage in thrombocytopenic patients.

(16) Technical Approach: Patients who had a platelet count less than 20,000 who were considered refractory to platelet transfusion and who had evidence of severe bleeding that appeared refractory to platelets were eligible for the study.

(17) Progress: The protocol was terminated due to lack of interest in giving patients AMICAR that were thrombocytopenic.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#:81/111 (3) Status: terminated

(4) Title: Comparative effect of major corticosteroids on lymphocyte blastogenesis and assessment of the corticosteroid sparing effect of troleandomycin

(5) Start Date: 1981	(6) Est Compl Date: 1984
(7) Principal Investigator: James S. Brown, LTC, MC	(8) Facility: FAMC Dept. of Clinical Investigation
(9) Dept/Svc: Medicine/Allergy	(10) Assoc Investigators: W. Ronald Tipton, COL, MC R. Stephen Whitaeker, CPT, MSC
(11) Key Words: corticosteroids lymphocyte blastogenesis dosage of steroids	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

NA

(15) Study Objective: To determine if various classes of corticosteroids differ in magnitude of suppression of lymphocyte blastogenesis and to ascertain the effect of troleandomycin in combination with these corticosteroids on lymphocyte blastogenesis.

16) Technical Approach: This is an in vitro study using normal lymphocyte populations for blastogenesis as triggered by mitogens and measured by incorporation of titrated thmidine.

(17) Progress: Relevant potency of various corticosteroids have been determined. In addition, the effect of troleandomycin has been tested and found not to have any effect in this system.

Publications: None

Presentations: Brown JS: The potency of various corticosteroids - inhibition of lymphocyte mitogenesis in humans. Presented: 35th Annual Carl W. Tempel Symposium, FAMC, Jan 83.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 81/109D (3) Status: Ongoing

(4) Title:

Southwestern Oncology Group Collaborative Studies

(5) Start Date:	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Arlene J. Zaloznik,M.D.,MAJ,MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words: Chemotherapy	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Sep 83 b. Review Results: To continue

c. Number of Subjects Enrolled During Reporting Period: 8

d. Total Number of Subjects Enrolled to Date: 19

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective:

Variable according to protocols involved.

(16) Technical approach:

Clinical approach

(17) Progress:

Patients are continuing to be registered on SWOG protocols with accumulation of data per the SWOG studies.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 81/ 106 (3) Status: ongoing

(4) Title: Clinical Effectiveness and Development of Subsensitivity with Chronic Administration of Atropine Sulfate

(5) Start Date: 1984	(6) Est Compl Date: 1984
(7) Principal Investigator: Harold S. Nelson, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Allergy	(10) Assoc Investigators: Robert Bowen, MAJ, MC Raymond Vaughan, CPT, MC
(11) Key Words: Atropine bronchodilator subsensitivity	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

To measure the bronchodilator response to atropine sulfate initially and then following two weeks of regular use.

(16) Technical Approach:

The bronchocilator response to nebulized saline and atropine sulfate will be measured for two hours on two separate days. Then, the subject will be given either saline or atropine sulfate to employ at home by nebulization four times daily. At the end of two eeeks the patient would return and receive the same medication that he would have employed for the previous two weeks and again pulmonary function response would be followed for two hours.

(17) Progress: None

Publications & Presentations: None

FAMC A P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 81/104 (3) Status: ongoing

(4) Title: The incidence of host defense deficiencies in patients presenting with frequent or prolonged infections.

(5) Start Date: 1981	(6) Est Compl Date: 1987-88
(7) Principal Investigator: W. Ronald Tipton, MD, COL, MC, Assistant Chief, Allergy Service	(8) Facility: FAMC Allergy-Immunology Service
(9) Dept/Svc: Med/Allergy	(10) Assoc Investigators:
(11) Key Words: immunodefiency infection laboratory tests	Harold S. Nelson, MD, COL, MC William Rickman, CPT, MSC Joseph Lima, BAC Fellows, Allergy-Immunology Service
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: 12

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

none

(15) Study Objective:
To determine the cost effectiveness of performing various laboratory evaluations of immune responsiveness in patients presenting with frequent or prolonged infections.

(16) Technical Approach: Patients who are referred for this protocol will have a standardized clinical evaluation by the Fellows in the Allergy-Immunology Service and will have a standard battery of tests performed to evaluate their immune status and phagocytic function. On the basis of the clinical history certain laboratory tests will be determined to have been clinically indicated. Subsequently, the yield from the battery of routine tests will be conpared to the yield from those tests which were thought to have been clinically indicated.

(17) This protocol is continuing. We have now enrolled 12 patients. It is anticipated that it will take approximately 5-6 years to accumulate enough patients to complete the protocol.

No publications or presentations.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as ammended)
CONTINUATION SHEET

(1) DATE: 30 Sept 84 (2) Protocol WUæ 81-101 (3) Status: Ongoing

(17) Results of this phase of the study were presented by CPT Peter McNally (medicine resident) at the 13th Annual William Beaumont Gastrointestinal Symposium in April 1984. The enclosed copy of the manuscript has been submitted for publication.

Pending review of study results to this date and discussion with the Immunology Service, Department of Clinical Investigation, FAMC, the undersigned officer will request an addemdum and extension to provide ongoing study of this area.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 81-101 (3) Status: Ongoing(see below)
(4) Title:
Development and evaluation of rapid immunodiagnostic procedures for the diagnosis of Giardiasis.

(5) Start Date: 5 May 1981	(6) Est Compl Date: May 1984(request extension)
(7) Principal Investigator: Thomas G. Brewer, M.D., LTC,MC	(8) Facility: FAMC FAMC
(9) Dept/Svc: Gastroenterology/DCI	(10) Assoc Investigators:
(11) Key Words: Diarrhea, Giardiasis Giardia Lamblia immunodiagnosis	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: May 1984 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: None
d. Total Number of Subjects Enrolled to Date: Forty-four
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A - no drug administration

(15) Study Objective:
To develop immunodiagnostic procedures for rapid detection of Giardia lamblia antigen in fecal and duodenal aspirate specimens and detection of anti-Giardia antibodies in the serum of patients infected with Giardiasis. To evaluate the efficacy of these tests for rapid diagnosis of Giardiasis in a select patient population.

(16) Technical Approach: We have not deviated from the technical approach described in detail in the protocol except for an alteration of the protocol in which patients undergoing diagnosis of Giardiasis by the use of enterotest string procedure are asked to undergo a followup enterotest examination after treatment with medication of the primary physician's choice. Ammendment to the patient consent form which includes this alteration had been previously forwarded and cleared through the Chief, Judge Advocate's Office, FAMC (25 Oct 83).

(17) Progress: Immunofluorescent antibody test on the sera of 38 patients with confirmed Giardiasis was performed by Dr. G.S. Visvesvara at the Parasitic Disease Branch, Center for Disease Control, Atlanta, GA. Results of the IFA test are noted in the enclosed copy of a manuscript which is currently submitted for publication. Results of the antibody test revealed that IFA is only of moderate sensitivity in the detection of Giardiasis (45%) but was significantly higher in patients with severe illness (greater than 10-lb weight loss) regardless of duration of illness.

(17) Progress:

Complete data compiled on 25 patients with the data on one other patient pending. Data on 8 patients is incomplete and/or mission, and hence these patients will not be included in this statistical analysis. Aside from a paper submitted for the Hugh Mahon Lectureship Award in June 1983, the only other paper to date from this research was an abstract entitled "Comparison of Thyrotopin Releasing Hormone Bolus in Infusion Testing in Patients With Subclinical Hypothyroidism" which appeared in Clinical Research, Vol. 32, No. 1, February 1984, page 19a. At present, laboratory data is pending on one patient and it is felt that one or two further control patients can be recruited during the next 6 to 7 months before completing the study and preparing a final paper. It is anticipated that the study will be concluded by July 1985.

PUBLICATIONS:

1. Bornemann, M.: Pitfalls in Mild Subclinical Hypothyroidism: Comparison of the TRH Bolus and Infusion. Submitted for Hugh Mahon Lectureship Award, FAMC, May 1983.

2. Bornemann, M., Kidd, G.S., and Hofeldt, F.D.: Comparison of Thyrotropin Releasing Hormone Bolus and Infusion Testing in Patients with Suspected Subclinical Hypothyroidism. (Abst.) Clin. Res. 32:1, 1984.

PRESENTATIONS:

1. Bornemann, M., Kidd, G.S., and Hofeldt, F.D.: Comparison of Thyrotropin Releasing Hormone Bolus and Infusion Testing in Patients with Suspected Subclinical Hypothyroidism. Presented: Western Section, Western Meeting, Carmel, CA, February 1984.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 80/121 (3) Status: Ongoing

(4) Title: An Evaluation of Pituitary and Thyroid Hormonal Responses to a 4-Hour Continuous and a Bolus Intravenous Infusion of TRH as a Useful Test of Thyroidal Functional Reserve

(5) Start Date: March 1981 (6) Est Compl Date: July 1985

(7) Principal Investigator:
Michael Bornemann, MD, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Medicine/Endocrine

(10) Assoc Investigators:
Gerald S. Kidd, MD, LTC, MC
William J. Georgitis, MD, MAJ, MC

(11) Key Words:
thyroid functional reserve
pituitary
thyroid axis
TRH infusion

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this rep rt.

(14) a. Date, Latest HUC Review: 9/83 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 5

d. Total Number of Subjects Enrolled to Date: 34

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None

(15) Study Objective:

The objective of this study is to determine if the diagnosis of mild or subclinical hypothyroidism can be more clearly established by some integrated parameter reflecting both the pituitary and thyroidal reserve responses to intravenous thyrotopin releasing hormone.

(16) Technical Approach:

Three groups of subjects will be evaluated in this protocol. Group 1 will consist of normal control patients; Group 2 will consist of patients with mild hypothyroidism diagnosed by an elevated TSH level but normal thyroid hormone levels; Group 3 will consist of patients with the Thyroid Clinic with high-normal TSH values and normal thyroid function tests, but who are clinical suspects of having mild hypothyroidism. The patients will undergo two TRH infusion tests in a random manner consisting of conventional bolus administration of 500 ug of TRH solution and the constant infusion of TRH over a 4-hour period with 500 ug of TRH diluted in normal saline and diffused at a rate of 2 ug per minute over the 4 hours using a Harvard infusion pump. The TSH values in the various groups of patients will be determined and statistically analyzed for differences between the groups.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 80/120 (3) Status: Ongoing

(4) Title: Evaluation of Carbohydrate Metabolism in Thyrotoxicosis: Investigations Into the Frequency, Type and Mechanisms of Carbohydrate Tolerance

(5) Start Date: April 1981 (6) Est Compl Date: October 1985

(7) Principal Investigator:

Gerald S. Kidd, MD, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Medicine/Endocrine

(10) Assoc Investigators:

T. P. O'Barr, Ph.D., DAC
Fred D. Hofeldt, MD, COL, MC (ret)
Robert J. Sjoberg, MD, CPT, MC

(11) Key Words:

carbohydrate intolerance
thyrotoxicosis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period: 3

d. Total Number of Subjects Enrolled to Date: 10 (only 4 of these have completed)

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A

(15) Study Objective:

The first objective of the study is to determine the frequency and reversibility of carbohydrate intolerance in thyrotoxicosis and to determine the importance of gut factors by doing oral and intravenous glucose tolerance tests. The second objective is to study the mechanisms of carbohydrate intolerance. This objective will be approached by measuring glucose, insulin, glucagon and free fatty acids, basally and after oral or intravenous glucose and by measuring the responses to exogenous insulin.

(16) Technical Approach:

Ten non-diabetic patients who are taking no medications, are less than age 45, are less than 120% of ideal body weight, will be studied while thyrotoxic and after recovery. Each patient will have an oral and an intravenous glucose tolerance test. Each patient will have an insulin tolerance test basally and following glucose infusion.

(17) Progress:

In FY84, 3 new patients have been studied during thyrotoxic phase but only 4 of the total (10) have been retested during the euthyroid phase. Many delays have been encountered but progress continues.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 80/118D (3) Status: Ongoing

(4) Title:
5-Azacytidine in the Treatment of Acute Nonlymphocytic Leukemia

(5) Start Date: Nov 80	(6) Est Compl Date: Unknown
(7) Principal Investigator: Arlene J. Zaloznik,M.D.,MAJ,MC	(8) Facility: FAMC
(9) Dept/Svc Medicine/Hema-Oncology	(10) Assoc Investigators:
(11) Key Words: 5-Azacytidine, Acute leukemia	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Sep 83 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 6

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". No adverse drug reactions.

(15) Study Objective:

To determine the efficacy of 5-Azacytidine in patients with acute nonlymphocytic leukemia who have relapsed after conventional chemotherapy.

(16) Technical Approach:

Patients who have proved to be refractory to standard forms of acute leukemia are given 5-Azacytidine in an attempt to induce remission

(17) Progress:

Although no patients have been registered during the last year it is recommended that this protocol continue to be open for patients with refractory leukemia until such time as 5-Azacytidine becomes commercially available.

Publications and Presentations: None

PUBLICATIONS for FY 84 Annual Progress Report Proto No. 81/117

SERVICE Endocrine DEPARTMENT Medicine

(1) McDermott M., Kidd, G., Blue, P., et al.: Bone mineral content in totally thyroidectomized patients; possible effect of calcitonin deficiency. (Abst.) 64th Meeting of the Endocrine Society, San Francisco, California, June 1982.

(2) McDermott, M.T., Kidd, G.S., Blue, P., Ghaed, V., and Hofeldt, F.D.: Reduced Bone Mineral Content in Totally Thyroidectomized Patients: Possible Effect of Calcitonin Deficiency. J. Clin. Endocrinol. Metab. 56:936-939, 1983.

PRESENTATIONS:

(1) McDermott, M.T.: Bone Mineral Content in Totally Thyroidectomized Patient. Presented: Uniformed Services Society of Endocrinology, San Francisco, CA, June 1982.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#:81/118 (3) Status: Ongoing

(4) Title:

Hypothalamic Pituitary Gonadal Function in Hypothyroidism

(5) Start Date: 3 September 1981

(6) Est Compl Date: Indefinite

(7) Principal Investigator:

Michael T. McDermott, MD, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Medicine/Endocrine

(10) Assoc Investigators:

Gerald S. Kidd, MD, LTC, MC
Fred D. Hofeldt, M.D.

(11) Key Words:

hypothyroidism
HPG axis
GONADAL FUNCTION

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Nov 82 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 1

d. Total Number of Subjects Enrolled to Date: 1

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None.

(15) Study Objective:

The objectives of this protocol are to define more clearly the mechanisms of gonadal dysfunction occurring in hypothyroidism and to see if these abnormalities resolve after treatment of the hypothyroid state.

(16) Technical Approach:

A prospective study to assess in a pair manner results of alterations in HPG axis as a consequence of hypothyroidism when evaluated with GnRH infusion and TRH testing, clinical stimulation and HCG testing in males and females.

(17) Progress:

One patient has been studied and her frozen serum has not yet been assayed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 81/119 (3) Status: Completed

(4) Title:

The Effect of Thyrotropin Releasing Hormone on Gonadotropin Releasing Hormone Stimulated Gonadotropin Secretion

(5) Start Date: March 1983 (6) Est Compl Date: March 1984

(7) Principal Investigator:
Michael T. McDermott, MD, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Medicine/Endocrine

(10) Assoc Investigators:
Gerald S. Kidd, MD, LTC, MC
Fred D. Hofeldt, MD

(11) Key Words:
gonadotropin releasing hormone
Thyrotropin releasing hormone

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Nov 82 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 8

d. Total Number of Subjects Enrolled to Date: 8

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None.

(15) Study Objective:

In order to gain a better insight into the mechanism of gonadal dysfunction in hypothyroidism, the objective of this protocol is to study the effect of a thyrotropin releasing hormone (TRH) infusion on basal and gonadotropin releasing hormone (GnRH) stimulated gonadotropins in normal subjects.

(16) Technical Approach:

Ten normal males will be studied with either a normal saline infusion or a TRH infusion. During these infusions, GnRH will be given as a bolus with measurement of appropriate hormones to determine interaction between releasing hormones.

(17) Progress:

Eight subjects have completed the study. Raw data is awaiting statistical analysis.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#:81-121-N (3) Status: Ongoing

(4) Title: IgA Nephropathy: A Prospective Evaluation

(5) Start Date: Dec. 81	(6) Est Compl Date: Dec 85
(7) Principal Investigator: JAMES A. HASBARGEN, MD MAJ, M.C. Chief, Nephrology Service	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Nephrology	(10) Assoc Investigators:
(11) Key Words: IgA nephropathy, Berger's Disease, prospective evaluation	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 6
d. Total Number of Subjects Enrolled to Date: 20
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To determine pathologic and clinical pathologic criteria for the diagnosis of IgA nephropathy, prognosis of patients with such a diagnosis, suitability for continued military service. The extent of the evaluation and degree of follow up required for such patients, and the sensitivity and specificity of various non-invasive diagnostic techniques which potentially could obviate the necessary for renal biopsy.

(16) Technical Approach: Patients who meet patient selection criteria established in protocol enrolled and subjected to the following: skin biopsy, serum IgA level, IgA coated peripheral lymphocyte analysis, and HLA typing. In addition, a kidney biopsy is closely scrutinized and the patient examined reference symptoms accompanying their disease and other associated symptomatology. Follow up is conducted indefinitely at six month intervals and if patient develops a marked decrease in renal function, kidney biopsy is repeated. Repeat skin biopsy is accomplished only for episodes of gross hematuria.

(17) Progress: Total of 20 patients have been enrolled including 6 during the past year. The study represents a collaborative effort utilizing WRAMC, DDEAMC, and recently Brooke AMC. Thus far approximately 50 patients have been enrolled totaling the study amongst the centers, and abstraction and presentation based on data gained from this protocol as well as the hematuria protocol are noted in the accompanying paper. Due to failure of laboratory freezer, the IgA coated lymphocyte portion of this study has suffered a major setback. It is anticipated that several more papers will ensue over the accompanying several years. Follow up of the patients in the protocol will be indefinite.

PRESENTATIONS FOR FY 84 Annual Progress Report Proto No. 81-121-N

SERVICE Nephrology DEPARTMENT Medicine

1. Presentation at 9th International Congress of Nephrology, Los Angeles, California, June 1984.

2. Tapp, D., Copley, J. Hasbargen, J. Moore, J. Gouge, S., Antonovycht, V. and Guggenheim, S.: IgA Nephropathy and Pathologic Correlation. Presented Current Concepts in Internal Medicine. San Francisco, CA, Oct. 84

Publications:

1. Copley, J.B., Hasbargen, J.A.: "Primary" Hematuria: A Prospective Evauation. Kidney International, 25: 161, 1984 (Abstract)

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#:81-122/N (3) Status: DISCONTINUED

(4) Title:

Utility of Furosemide in Early Oliguric or Non-Oliguric Renal Failure

(5) Start Date: Feb. 82	(6) Est Compl Date: Oct 84
(7) Principal Investigator: JAMES A. HASBARGEN, MD MAJ, M.C.	(8) Facility: FAMC
(9) Dept/Svc:Medicine/Nephrology	(10) Assoc Investigators: JACK MOORE, JR., MAJ, M.C. Chief, Nephrology Service, WRAMC ROBERT W. SCHRIER, MD Chief, Department of Medicine Univ. of Colo. Health Sciences Center
(11) Key Words: Furosemide, oliguric, renal failure	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 1

d. Total Number of Subjects Enrolled to Date: 8

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To prospectively determine if Furosemide is capable of producing diuresis and thereby attentuating the severity of acute renal failure when administered early in the course of oliguria. An additional purpose is to determine if non-oliguric acute renal failure patients would benefit from Furosemide therapy; to determine if their need for dialysis could be decreased.

(16) Technical Approach: Patients accepted for the protocol per parameters listed therein are randomized into two therapeutic trial groups, Furosemide or Saline. Patients are then given specific doses by weight of Furosemide or specific amounts of Saline and their responses to same is monitored immediately and over ensuring days.

(17) Progress: This study represents a collaborative study between the Renal Division, University of Colorado Health Sciences Center and Departments of Nephrology, WRAMC, William Beaumont AMC, and FAMC. Fitzsimons has provided a total of 7 patients for this study group since approval of the protocol. It is too early to determine utility of Furosemide and it is anticipated a relatively large number of patients will need to be enrolled in this study to stratify the multiple variables encountered.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 81/123 (3) Status: Ongoing

(4) Title:

Primary Renal Hematuria: A Prospective Evaluation

(5) Start Date: Feb. 82	(6) Est Compl Date: Feb 85
(7) Principal Investigator: JAMES A. HASBARGEN, MD MAJ, M.C. Chief, Nephrology Service	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Nephrology	(10) Assoc Investigators:
(11) Key Words: primary renal hematuria, prospective evaluation	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 3

d. Total Number of Subjects Enrolled to Date: 9

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To determine the etiology and significance of hematuria microscopic and macroscopic, as well as prognosis in patients who have neither personal or family history of renal disease, nor evidence of systemic disease or extra renal causes of hematuria.

(16) Technical Approach: Patients who meet established criteria contained within the protocol are evaluated with skin biopsy, serum IgA levels and IgA coated peripheral lymphocytes. Most patients then undergo renal biopsy and/or renal arteriography (dependent upon age). HLA typing is accomplished on all patients and patients are followed every six months for an indefinite period of time regardless of renal biopsy findings to determine the course of their disease

(17) Progress: This study represents a collaborative study with Walter Reed AMC, Eisenhower AMC, possibility of Beaumont AMC, and Brooke AMC participating in addition to FAMC. It is hoped that over a three year period at least 50 individuals will be enrolled in the protocol. Fitzsimons has thus far contributed a total of 9 patients with a goal of 50 patients which can be reached over a three year period.

PUBLICATIONS for FY 84 Annual Progress Report Proto No. 81/123

SERVICE Nephrology DEPARTMENT Medicine

1. Copley, J.B., and Hasbargen, J.A. "Primary" Hematuria: A Prospective Evaluation (Abstract). Kidney International. (In Press)

Presentations:

1. Copley, J.B., and Hasbargen, J.A. "Primary" Hematuria: A Prospective Evaulation. Kidney International, 25: 161, 1984. Presented to American Society of Nephrology Conference, December 1984

DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &
HSPA-I Ltr,
8 July 1982

(1) Date: FY 1984 (2) Protocol WU Nr.: 81/124 (3) Status: Terminated

(4) Title:
INTRA-CORONARY STREPTOKINASE
IN EVOLVING MYOCARDIAL INFARCTION

(5) Start Date: December 1981	(6) Est Compl Date: 1983
(7) Principal Investigator KENNETH E. TRNKA MD MAJ MC	(8) Facility: FAMC
(9) Dept/Svc: Dept of Med,Card Svc	(10) Assoc Investigators: Richard C. Davis JR MD PhD LTC MC CARLOS A. MENDOZA MD MAJ MC
(11) Key Words: Intra-Coronary Streptokinase Acute Myocardial Infarction	
(12) Accumulate MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: unknown b. Review Results:

c. Number of subjects enrolled during reporting period: 23

d. Total number of subjects enrolled to date: 23

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet, designating this continuation as (14)c.)

(15) Study Objective:

To assess the efficiency and safety of intra-coronary streptokinase infusions in patients with acute myocardial infarction.

(16) Technical Approach:

After initial evaluation of each patient who gives informed consent to the study protocol, the following procedures are performed: complete medical history, complete physical exam, chest x-ray, EKG, CBC chemistry profile, myocardial isoenzymes, PT, PTT (see continuation sheet)

(17) Progress:

Since initiation of protocol in December 1981, a total of 23 patients have been entered under the protocol. Analysis has shown a trend toward improvement in LV function. Using a total dose of 160,000 units of Streptokinase administered intra-coronary showed a significant drop in fibrinogen levels and prolongation of the thrombin time. This data was (see continuation sheet)

Continuation sheet:

(16) thrombin time, fibrinogen level, UA. Right and left heart catheterization is then performed to include hemodynamic parameters, left heart ventriculogram and selective coronary angiography. After locating a totally obstructed coronary artery, 1c NTG is given followed by 1c streptokinase consisting of a 10,000 unit bolus and 2500 units/ minute for a total of 60 minutes. Repeat LV ventriculogram is performed with repeat hemodynamic measurements. The patient is then taken to the CCU for routine post MI treatment.

(17) Presented at the Army Cardiology Meeting in May 1982 and May 1983. No technical problems have arisen with the procedure. Two patients died who were entered in the protocol, one 12 hours after the procedure with an extensive anterior MI and the second patient at 72 hours with an extensive anterolateral MI. Both patients are felt to have died from the extensive myocardial infarction and not from the procedure.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#:81-125 (3) Status:Ongoing

(4) Title:
Flexible Fiberoptic Esophageal Vein Sclerosis: A Multi-Center Study

(5) Start Date:September 1981	(6) Est Compl Date:June 1984
(7) Principal Investigator: Thomas G. Brewer, MD, LTC, MC	(8) Facility: FAMC FAMC(participating facilities include the University of Colorado Medical Center, Denver Veteran's Hospital, and Denver General Hospital)
(9) Dept/Svc:Medicine/GI Service	(10) Assoc Investigators:
(11) Key Words: Esophageal varices, upper gastrointestinal hemorrhage fiberoptic vein sclerosis	None
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: March 1984 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: Five (5)

d. Total Number of Subjects Enrolled to Date: Forty (40)

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None

(15) Study Objective: To determine the therapeutic efficacy and safety of flexible fiberoptic vein sclrosis in preventing recurrent bleeding in patients with recent hemorrhage from esophageal varices.

(16) Technical Approach: We have not deviated from the technical approach to sclerosing esophageal varices as outlined in the protocol. Endoscopic sclerotherapy has been accomplished in all five patients entered in the study with a maximum number of sclerotherapies accomplished being nine in one study patient. Olympus single and double channeled panendoscopes have been used with Olympus and Medi Teck injectors which contain a retractable 23-gauge needle with 3% Sotradecol (Sodium Tetradecyl sulfate -TSS).

(17) Progress: Of the current total number of patients (noted above) entered from all centers into the study, we have entered 5 patients - all of whom have been randomized to the sclerosis group. Endoscopic esophageal vein sclerosis has been completed in each patient's case with complete ablation of varices and without occurrence of any major complication. There have been no mortalities in any of the patients entered in this study at FAMC since 1981 with a mean followup at this time of approximately 18 months. Transient substernal chest pain with occasional dysphagia lasting 24 to 48 hours has been noted in 4 of the cases at some point during the sclerotherapy regimen but has resolved in every case. As noted, all patients are currently alive and all but one patient continue clinical follow up with regular

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as ammended
Continuation Sheet

(1) DATE: 30 Sept 84 (2) Protocol WUæ: 81-125 (3) Status: Ongoing

(17) followup in the FAMC GI Clinic. One patient has discontinued followup as of June 1984 because of a move to a different state.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/100-N (3) Status: Ongoing

(4) Title: Combined Prednisone and Cyclophosphamide Therapy Coupled with Plasmapheresis In The Treatment of Anti-glomerular Basement Membrane (Anti-GBM) Antibody Induced Disease

(5) Start Date: Mar 82	(6) Est Compl Date: 86
(7) Principal Investigator: JAMES A. HASBARGEN, MD MAJ, M.C. Chief, Nephrology Service	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Nephrology	(10) Assoc Investigators:
(11) Key Words: Prednisone, Cyclophosphamide, Plasmapheresis, anti-GBM antibody induced disease	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To determine if Prednisone and Cyclophosphamide alone or in combination with plasmapheresis is efficacious in lowering circulating anti-GBM bi-levels and thereby affecting the clinical course of anti-GBM induced nephritis. In addition, it is desirable to learn if treatment with Prednisone and Cytotoxin with or without plasmapheresis has a role in the prevention of, or is therapeutic for pulmonary manifestations of anti-GBM induced disease.

(16) Technical Approach: Patients with anti-GBM antibody disease are randomized into one to two treatment groups consisting of Prednisone and Cyclophosphamide alone or in combination with plasmapheresis. Patients are monitored with history, physical, hematologic and chemistry monitoring to include renal function parameters as well as anti-GBM antibody titers. Criteria for withdrawl from the study as well as analysis of the study are indicated within the protocol.

(17) Progress: AntiGBM_{Ab} mediated pulmonary-renal disease is a rare entity which accounts for the collaborative nature of the study between FAMC, WRAMC, National Naval Medical Center and NIH. Thus far since inception of protocol, FAMC has not had any patients who met entry into the protocol standards. It is anticipated over the next several years that we will be able to contribute one to two patients to the protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/101-N (3) Status: Ongoing

(4) Title:
teroid And Immunosuppressive Drug Therapy In Idiopathic Crescentic Glomerulonephritis

(5) Start Date: Apr 82	(6) Est Compl Date: Apr 85
(7) Principal Investigator: AMES A. HASBARGEN, MD AJ, M.C.	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Nephrology	(10) Assoc Investigators: JAMES E. BALOW, M.D. and HOWARD A. AUSTIN, MD National Institutes of Health Bethesda, Maryland
(11) Key Words: steroid mmunosuppressive drug, idiopathic rescentic, glomerulonephritis, apidly progressive glomerulonephritis	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 0

d Total Number of Subjects Enrolled to Date: 1

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective: To compare the efficacy of intravenous methylprednisolong vs. intravenous cyclophosphamide in the treatment of idiopathic crescentic glomerulonephritis. Comparison will be made of the number of favorable outcomes of renal function and renal pathology as well as as drug related toxicities manifested by each treatment group at the time of the 6 study month.

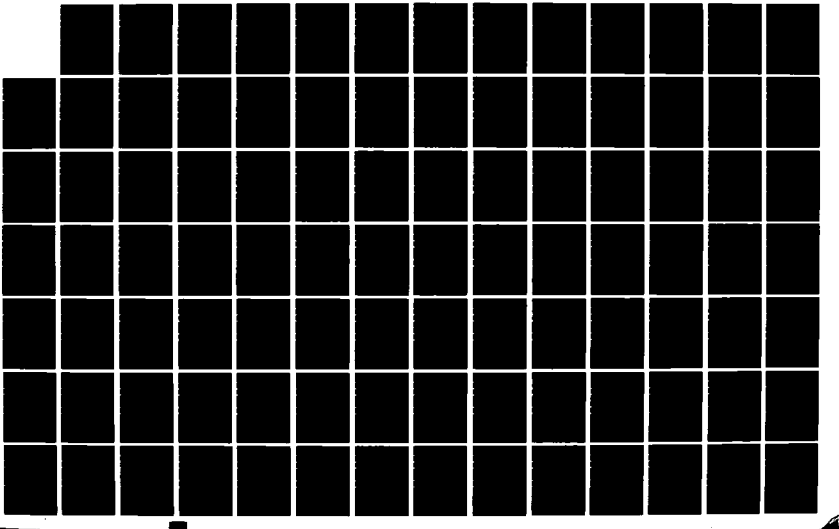
(16) Technical Approach: Patients with idiopathic crescentic glomerulonephritis are randomized into one of two study groups to receive either monthly intravenous pulse methylprednisolong for six months or monthly intravenous pulse cyclophosphamide for 6 months. All patients are treated with oral prednisolone in addition. Effects of therapy are monitored with frequent histories and physical examinations as well as hematologic, urinalysis and renal function monitoring. At the end of 6 months a second renal biopsy is accomplished to determine the effect of the above mentioned therapy. Criteria for withdrawal from the study, retreatment of patients who exacerbate their course of glomerulonephritis, and analysis of the study are as indicated in the study protocol.

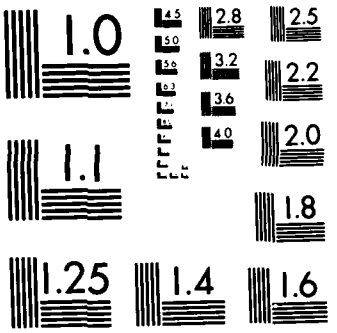
(17) Progress: Idiopathic crescentic glomerulonephritis is a rare disease, and it is for this reason this protocol represents a collaborative effort between FAMC, WRAMC, and NIH. Since the inception of the protocol one patient at FAMC has been enrolled and was randomized to the pulse methyprednisolone group.

Publications and Presentations: None

AD-A154 658 CLINICAL INVESTIGATION PROGRAM ANNUAL PROGRESS REPORT 2/3
(U) FITZSIMONS ARMY MEDICAL CENTER AURORA CO 30 SEP 84

UNCLASSIFIED F/G 6/5 NL





DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &
HSPA-I Ltr,
8 July 1982

(1) Date: FY 1984 (2) Protocol WU Nr.: 82/103 (3) Status: Terminated

(4) Title:

A Survey of Lymphocyte Subpopulations in Patients with Malignancies

(5) Start Date: April 1982	(6) Est Compl Date: March 1984
(7) Principal Investigator Nicholas J. DiBella, M.D. and R. S. Whiteaker, Ph.D.	(8) Facility: FAMC Hematology/Oncology Service and inpatient wards
(9) Dept/Svc: Hem/Onc & DCI	(10) Assoc Investigators: Stephen G. Oswald, D.O.
(11) Key Words: Lymphocytes Neoplasia	
(12) Accumulate MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of subjects enrolled during reporting period: _____

d. Total number of subjects enrolled to date: 44

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: N/A

(Continue on a separate sheet, designating this continuation as (14)c.)

(15) Study Objective:

To determine if there are any abnormalities of peripheral blood lymphocyte populations in patients with malignancies.

(16) Technical Approach:

Monoclonal antibody markers were applied to peripheral blood lymphocytes of patients prior to treatment and normal controls.

(17) Progress:

Study has been terminated. To date, 22 patients and 11 controls have been studied. In general, the more advanced the stage of the cancer the greater the depression of total lymphocyte count. There was no consistent pattern of change noted in any of the monoclonal lymphocyte subtypes. It was concluded that further study of this problem would not provide any new useful information.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/104 (3) Status: Ongoing

(4) Title:

The Effect of Tamoxifen on Gynecomastia

(5) Start Date: 30 Sep 82	(6) Est Compl Date: March 1985
(7) Principal Investigator: Michael T. McDermott, MD, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators: Fred D. Hofeldt, MD Gerald S. Kidd, Md, ltc, mc
(11) Key Words: Tamoxifen gynecomastia therapy	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Feb 83 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 5

d. Total Number of Subjects Enrolled to Date: 5

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None.

(15) Study Objective:

The objective of this protocol is to evaluate, in a double-blind placebo controlled prospective trial, the effect of Tamoxifen on males with gynecomastia and to characterize any co-existent hormonal changes.

(16) Technical Approach:

A randomized, double-blind placebo controlled study of the effects of Tamoxifen therapy on idiopathic gynecomastia will be performed. Breast size will be assessed by photographs, palpation and measurement of tissue.

(17) Progress:

Five patients have entered the study. Two, with stage 5 gynecomastia, did not show objective reduction in breast size but one reported decreased tenderness. Two currently under study have not had the double-bline cod-revealed. One other failed to return for followup appointment.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/106 (3) Status: ongoing

(4) Title:
Clinical Usage of High Frequency Jet Ventilation

(5) Start Date: June 1981	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Michael Perry COL MC	(8) Facility: FAMC
(9) Dept/Svc: Pulmonary/Medicne	(10) Assoc Investigators:
(11) Key Words: High Frequency Jet Ventilation	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 2

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective: All patients with bronchopleural fistulae or who are difficult to ventilate with standard technique are candidates for thismode of ventilation. Assessment will be made concerning the efficacy of high frequency jet ventilation for the various clinical problems encountered.

(16) Technical Approach: A standard VS 600 Jet Ventilator will be used, with an injection catheter placed into the endotracheal tube. Adjustment of driving pressures (up to #50/sq in) will be made along with I:E ratio and frequency (up to 200/min)to determine the optimum settings for maximum ventilation and oxygenation.

(17) Progress: Since approval human use has been unavailable because of the too stringent protocol criteria. The portocol has been modified to allow entry of patients not truly moribound to allow for a more meaningful experience. Extensive work has been performed in the facilities of the clinical investigation service using animals with this ventilator which we hope to apply to the patients entering this protocol after modifications have been approved.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/107 (3) Status: Terminated

(4) Title: Interstitial Lung Disease Protocol

(5) Start Date: June 1981	(6) Est Compl Date: Terminated
(7) Principal Investigator: Gary R. Ripple, MD CPT, MC	(8) Facility: FAMC
(9) Dept/Svc: DOM/Pulmonary	(10) Assoc Investigators: Michael E. Perry, LTC, MC Jimmy Gilbert, MAJ, MC William Strampel, MAJ, MC Michael Schlachter, CPT, MC
(11) Key Words: corticosteriod gallium seitigraphy interstitial lung disease bronchoalveolar lavage open lung biopsy	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: June 83 b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 4

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None.

(15) Study Objective: Through the correllation of gallium scitigraphy, bronchoalveolar lavage, open lung biopsy and pulmonary function testing, the investigators are striving to determine the role of immune complexes and neutrophils in the pathogenesis and treatment (with corticosteroids) of interstitial lung disease.

(16) Technical Approach: Consenting patients with interstitial lung disease (ILD) are evaluated initially by gallium scintigraphy, bronchoalveolar lavage, pulmonary function studies and open lung biopsy. Those patients having ILD of undetermined etiology on biopsy are re-evaluated by gallium scanning, bronchoalveolar lavage, and pulmonary function studies 6 weeks after biopsy (before steroids) and after 6 weeks of steroids. The purpose is to correlate disease activity with diagnostic procedures.

(17) Progress: Terminated

Publications and Presentations: none

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/109 (3) Status: Ongoing

(4) Title: Correlation of Birth Weight with Maternal Hemoglobin S. Concentration: A Retrospective Study

(5) Start Date: 1982	(6) Est Compl Date: Indefinite
(7) Principal Investigator: John R. Hess, MD, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc:Hema/Oncol/MED	(10) Assoc Investigators: J. Benjamin Hall, MAJ, MC; Lynn G. Stansbury, MD, DAC; Nicholas J. DiBella, COL, MC; Jay M. Hill, COL, MC
(11) Key Words: hemoglobin S; sickle cell trait	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: a) To reaccess the association of maternal sickle cell trait and low infant birth weight. b) To correlate infant birth weight with maternal hemoglobin S concentration.

(16) Technical Approach: The relation of infants birth weight to their mothers' levles of Hb S and duration of gestation will be accessed with the techniques of linear and multiple linear regression or analysis of variance and covariance. Difference will be judged significant at the .05 level.

(17) Progress: The numbers are too small and the study will need to continue for 3 to 4 years for additional comparative statistics.

Publications and Presentations: none

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/110 (3) Status: completed

(4) Title: An investigation of immunologic reaction to human serum albumin.

(5) Start Date: 1982	(6) Est Compl Date: completed 1984
(7) Principal Investigator: HS Nelson, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Allergy	(10) Assoc Investigators: JS Brown, LTC, MC
(11) Key Words: human serum albumin Immunologic reaction	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period: 100
d. Total Number of Subjects Enrolled to Date: 200
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". none

(15) Study Objective:
To determine whether allergy patients receiving injections of allergy extracts containing human serum albumin develop evidence of IgE or IgG antibodies directed toward human serum albumin.

(16) Technical Approach: Patients at three Army medical centers who have been receiving injections of allergy extracts containing 0.03% human serum albumin were skin tested with a diluent containing the same concentration of albumin,and blood was drawn from every tenth patient for in vitro studies. These consisted of assays for IgG antibodies in a microtiter system.

(17) Progress: A total of somewhat over 200 patients were skin tested. None had any evidence of IgE mediated reactivity. Approximately 45 serum samples were collected and evaluated for the presence of IgG antibody and none was detected.

Publications: Brown JS, Ledoux R, Tipton WR, Nelson HS: An investigation of the immunologic reaction to human serum albumin (abst). Ann allergy 52:221;1984.

PRESENTATIONS FOR FY 84 Annual Progress Report Proto No. 82/110

SERVICE Allergy DEPARTMENT Medicine

Brown JS: Evaluation of possible immunologic response to human serum albumin in allergy extracts. Presented: Carl W. Tempel Allergy-Immunology and Pulmonary Symposium, Fitzsimons AMC, 26 Jan 84.

Brown JS: An investigation of the immunologic reaction to human serum albumin. Presented: 40th annual congress of the American College of Allergists, San Francisco, CA, 7 Apr 84.

Brown JS: An investigation of the immunologic reaction to human serum albumin. Presented: 2nd Annual Aspen Allergy Conference, Aspen, CO, 28 July 1984.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/111D (3) Status: ongoing

(4) Title: Investigation of the efficacy and side effects of oral and inhaled beta adrenergic bronchodilators in patients on optimal theophylline therapy.

(5) Start Date: 1983	(6) Est Compl Date: 1984
(7) Principal Investigator: HS Nelson, MD, COL, MC	(8) Facility: FAMC Allergy-Immunology Clinic
(9) Dept/Svc: Medicine/Allergy	(10) Assoc Investigators: Mark Vandewalker, MAJ, MC
(11) Key Words: adrenergic bronchodilator subsensitivity	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 15

d. Total Number of Subjects Enrolled to Date: 25

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

none

(15) Study Objective: To determine whether the addition of oral or inhaled beta adrenergic medication to treatment with optimal doses of theophylline significantly improves the treatment of patients with bronchial asthma.

(16) Technical Approach: Patients will be placed on oral theophylline and either oral or inhaled terbutaline. They will then undergo a double-blind crossover of terbutaline and placebo. During this time pulmonary function and asthma symptoms and requirement for asthma medication will be monitored.

(17) Progress: Twenty-three patients completed the oral phase of the study. Most have now also completed the inhaled phase, which should be completed in several more months.

Publications: None

Presentations: Kray KT: Double-blind study of long-term oral terbutaline: Efficacy and side effects. Presented: 2nd Aspen Allergy Conference, Aspen, CO, 27 July 84.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/112 (3) Status: completed

(4) Title: The use of modified RAST in determining initial immunotherapy doses.

(5) Start Date: 1982	(6) Est Compl Date: 1984
(7) Principal Investigator: HS Nelson, MD, COL, MC	(8) Facility: FAMC Allergy-Immunology Service
(9) Dept/Svc: Medicine/Allergy	(10) Assoc Investigators:
(11) Key Words: immunotherapy modified RAST	David Moyer,CDR, MC, USN

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 46
d. Total Number of Subjects Enrolled to Date: 52
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

none

(15) Study Objective: To determine whether use of the modified RAST will allow initiation of allergy immunotherapy with more concentrated extracts than normally would be employed.

(16) Technical Approach: Patients in whom the decision had been made to institute immunotherapy, and who had a clearcut seasonal allergic history, had modified RAST performed to that allergen. An assessment was made based on the predicted starting dose whether the patient could have initiated immunotherapy by the modified RAST dosing schedule at a higher concentration than that customary schedule employed.

(17) Progress: Fifty-two patients were evaluated. It was found that there was no advantage to the modified RAST.

Publications: Moyer DB, Bowen R, Nelson HS: The use of the modified RAST in determining initial immunotherapy doses (abst) Ann Allergy 52:220; 1984.

PRESENTATIONS FOR FY 84 Annual Progress Report Proto No. 82/112

SERVICE Allergy-Immunology DEPARTMENT Medicine

Moyer DB: Prediction of allergy immunotherapy starting dose---use of the modified RAST. Presented: Carl W. Tempel Allergy-Immunology Pulmonary Symposium, Fitzsimons AMC, 25 Jan 84.

Moyer DB: The use of the modified RAST in determining initial immunotherapy doses. Presented: 40th Annual Congress of the American College of Allergists, San Francisco, CA, 7 Apr 84.

Moyer DB: The use of the modified RAST in determining initial immunotherapy doses. Presented: 2nd Aspen Allergy Conference, Aspen, CO 28 Jul 84.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/113 (3) Status: on going

(4) Title: The effect of inhaled corticosteroids on the development of beta adrenergic subsensitivity

(5) Start Date: not started	(6) Est Compl Date: indefinite
(7) Principal Investigator: HS Nelson, MD, COL, MC	(8) Facility: FAMC Allergy-Immunology Clinic
(9) Dept/Svc: Medicine/Allergy	(10) Assoc Investigators:
(11) Key Words: Corticosteroids beta adrenergic subsensitivity	RW Weber, COL, MC
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

none

(15) Study Objective: To determine whether the administration of inhaled corticosteroids in conjunction with inhaled beta adrenergic bronchodilators prevents the development of subsensitivity to the bronchodilator action of the beta agonists.

(16) Technical Approach: Patients will be tested for their response to inhaled terbutaline before and following a 3-week course of inhaled terbutaline or placebo administered in a double-blind, random crossover design.

(17) Progress: This study has been postponed until completion of the ketotifen beta adrenergic subsensitivity study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/114 (3) Status: Ongoing

(4) Title: Growth of Basal Cell Carcinoma Cells in Defined Medium and Study of their Growth and Immunological Characteristics.

(5) Start Date: Nov 82	(6) Est Compl Date: Oct 85
(7) Principal Investigator: Ronald E. Grimwood, M.D. LTC, MC	(8) Facility: FAMC DCI
(9) Dept/Svc: Dept of Med/Derm Svc	(10) Assoc Investigators: J. Clark Huff, M.D. Charles Ferris, CPT, MSC Richard A.F. Clark, M.D.
(11) Key Words: Basal Cell Carcinoma Defined Culture media for Keratinocytes	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: N/A b. Review Results: N/A

c. Number of Subjects Enrolled During Reporting Period: N/A

d. Total Number of Subjects Enrolled to Date: N/A

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective:

Growth and study of basal cell carcinoma cells in culture.

(16) Technical Approach: The approach to culturing of basal cells has, and will [illegible] use of the media formulated by Dr Ham's Lab at the University of Colorado Boulder termed MCDB 153. We have been successful to date in culturing normal human keratinocytes in this medium but not successful in culturing basal cell carcinomas. This has included an attempt utilizing fibronectin coated plates. We next will be attempting growth utilizing basal cell tumors that we have successfully grown in nude mice. There is experimental evidence with other tumors grown in nude mice to suggest that there is a greater success rate of in vitro culture once the tumors have been grown in the animal model.

(17) Progress: As stated above, progress has been made in the area of BCC tumor transplantation to nude mice which we hope will facilitate growing the tumor cells in culture (Protocol # 84/115). We also have available two CO_2 controlled incubators that are an absolute requirement for the propogation of keratinocytes as well as BCC cells.

(18) Presentations/Publications: None to date.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/115D (3) Status: on-going

(4) Title: The effect of oral ketotifen on the development of subsensitivity to beta agonists.

(5) Start Date: 1984	(6) Est Compl Date: 1985
(7) Principal Investigator: HS Nelson, MD, COL, MC	(8) Facility: FAMC Allergy-Immunology Clinic
(9) Dept/Svc: Medicine/Allergy	(10) Assoc Investigators:
(11) Key Words: ketotifen subsensitivity beta agonists	W Dolen, MAJ, MC RW Weber, COL, MC BT Miller, CPT, MC
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

none

(15) Study Objective: To determine whether the drug, ketotifen, can prevent the development of subsensitivity to inhaled beta agonists in humans.

(16) Technical Approach: The bronchodilator response to inhaled terbutaline will be measured before and following chronic terbutaline administration during two periods of time, one when the patients are receiving in addition oral ketotifen, the second when they are receiving a placebo.

(17) Progress: This study is ready to commence, but no patients have been enrolled to date.

Publications and Presentations: None

DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &
HSPA-I Ltr,
8 July 1982

(1) Date: FY 84 (2) Protocol WU Nr.: 83/114 (3) Status: terminated

(4) Title:

A Multi-centered, double-blind, randomized study of the steroid sparing effect of budesonide versus placebo in adult patients with chronic asthma.

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator (8) Facility: FAMC

Harold S. Nelson, MD, COL, MC

(9) Dept/Svc: Medicine/Allergy

(10) Assoc Investigators:
Robert Bowen, CPT, MC
William Long, MAJ, MC

(11) Key Words:

(12) Accumulate MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of subjects enrolled during reporting period:

d. Total number of subjects enrolled to date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.:

(Continue on a separate sheet, designating this continuation as (14)e.)

(15) Study Objective:

(16) Technical Approach:

(17) Progress:

This protocol was terminated before any patients had completed the study because of animal data which raised questions regarding its safety. Termination was at direction of the Food and Drug Administration. The safety question was raised due to an increase in brain tumors in a particular strain of mice from a normal 1% to 10% when they received injection of doses of this drug well in excess of anything which had been contemplated in human use.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/113 (3) Status: Ongoing

(4) Title: Growth of human Keratinocytes

(5) Start Date: Jul 83	(6) Est Compl Date: Jul 85
(7) Principal Investigator: RONALD E. GRIMWOOD, M.D., LTC,	(8) Facility: FAMC
(9) Dept/Svc: Dept of Med/Derm Svc	(10) Assoc Investigators: J. Clark Huff, M.D. Charles Ferris, PhD, MSC Phil O'Barr, PhD, DAC
(11) Key Words: Cell culture Keratinocytes	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: N/A

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

Growth and study of human keratinocytes in culture.

(16) TECHNICAL APPROACH: The technical approach as stated last year has been to grow human keratinocytes obtained from newborn foreskins in MCDB 153 serum free medium. This has been accomplished and cells have been successfully frozen down in liquid nitrogen and subsequently cultured. We have not accomplished the final phase which will be to attempt to identify specific antigens (i.e. bullous pemphigoid) expressed by these cells. This will be accomplished with SDS page gel electrophoresis and nitrocellulose transfer. (Dr. O'Barr's lab).

(17). PROGRESS: As stated above, we can successfully grow human keratinocytes and have been able to freeze the cells and subsequently culture these same cells from the frozen state. We have also utilized these cells for prostaglandin studies after they have been irradiated with ultraviolet light.

PUBLICATIONS AND PRESENTATIONS: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/112 (3) Status: Terminated

(4) Title: Steroid Therapy in Chronic Obstructive Lung Disease - Prediction of Response by Lung Mechanics

(5) Start Date: August 1983	(6) Est Compl Date: April 1984
(7) Principal Investigator: G. Keith Wolfe, M.D., CPT, MC	(8) Facility: FAMC
(9) Dept/Svc:Pulmonary/MED	(10) Assoc Investigators: Reuban M. Cherniack, MD, National Jewish Hospital E. Fernandez, MD, National Jewish Hospital
(11) Key Words:	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period: 10
d. Total Number of Subjects Enrolled to Date: 10
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". none

(15) Study Objective: Classification of degree of responsiveness to steroids based on detailed study of lung mechanics.

(16) Technical Approach: A double-blinded trial with methyl prednisolone versus placebo in consecutive 3 week periods with testing of lung mechanics, exercise performance and bronchial reactivity to histamine before, between consecutive trials and after the study.

(17) Progress: Study has been terminated short of desired number ofpatients. Non-blinded patients from National Jewish Hospital will also be studied (7 Pt's) before and after steroid (completed). Results are only now being tabulated and reviewed. Final results should be available by the end of 1984.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/109 (3) Status: Ongoing

(4) Title:
EARLY REGIONAL WALL MOTION ABNORMALITIES IN NON-TRANSMURAL MYOCARDIAL INFARCTION

(5) Start Date: Mar 1983	(6) Est Compl Date:
(7) Principal Investigator: Matthew J. McMahon DO MAJ MC	(8) Facility: FAMC
(9) Dept/Svc: Dept Medicine/Cardio Svc	(10) Assoc Investigators: RICHARD C. DAVIS, JR, MD, PhD, LTC, MC GUY N. PIEGARI, JR, MD, MAJ. MC
(11) Key Words: ECHOCARDIOGRAPHY MYOCARDIAL INFARCTION	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA
c. Number of Subjects Enrolled During Reporting Period: 17
d. Total Number of Subjects Enrolled to Date: 17
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

NA

(15) Study Objective:
To assess the utility of two-dimensional echocardiography in facilitating the early diagnosis of non-transmural myocardial infarction.

(16) Technical Approach:
Patients entering the FAMC CCU are given: 2-D echocardiography examination within 12 hours of admission. These studies are then evaluated for cardiac wall motion abnormalities. The study is applied only to those patients admitted for chest pain without obvious transmural MI.

(17) Progress: Data on 17 patients has been accumulated. This represents approximately half the minimum number of subjects desired. The study is presently ongoing in the data collection stage in the fiscal year 1984.

PUBLICATIONS AND PRESENTATIONS: None.

DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &
HSPA-I Ltr,
8 July 1982

(1) Date: FY April 84 (2) Protocol WU Nr.: 83/108 (3) Status: Terminated

(4) Title: Multicenter, Double-Blind, Randomized, Parallel Comparison of Two Different Dosage Regimens of Naproxen Sodium in Patients with Bone Pain Due to Metastatic Cancer

(5) Start Date: Jan 83 (6) Est Compl Date: Terminated

(7) Principal Investigator (8) Facility: FAMC
Arlene J. Zaloznik, M.D., MAJ, MC

(9) Dept/Svc: Hematology/Oncology (10) Assoc Investigators:
Nicholas J. DiBella, M.D., COL, MC

(11) Key Words:
Naprosyn
Bone pain
Metastatic cancer

(12) Accumulate MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____
c. Number of subjects enrolled during reporting period: 0
d. Total number of subjects enrolled to date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: Not applicable

(Continue on a separate sheet, designating this continuation as (14)e.)

(15) Study Objective:
To compare the relative efficacy and safety of a higher total dose of Naproxen Sodium to a lower total daily dose in patients with moderate to severe persistent bone pain due to metastatic cancer.

(16) Technical Approach:
Patients are randomized to receive either high dose or low dose Naproxen Sodium for three days to control severe persistent bone pain.

(17) Progress:
Because of some inherent problems in the design of the protocol, no patients have been registered. A meeting was held with the people from Syntex Laboratories to resolve some of these problems. They were unresolvable and the protocol was terminated without any patients having been registered.

(2)

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/107 (3) Status: ONGOING

(4) Title: USE OF ISOTRETINOIN IN PREVENTION OF BASAL CELL CARCINOMA.

(5) Start Date: APP 1 Oct 84

(6) Est Compl Date: 5 years from start.

(7) Principal Investigator:
J. RAMSEY MELLETTE, M.D., COL, MC

(8) Facility: FAMC
DERMATOLOGY SERVICE

(9) Dept/Svc: Medicine/Dermatology

(10) Assoc Investigators:
LINDA M. SERWATKA, MAJ, MC Co-Principal Investigator.

(11) Key Words: Isotretinoin
Retinoids
Basal cell carcinoma

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: N/A b. Review Results: N/A

c. Number of Subjects Enrolled During Reporting Period: N/A

d. Total Number of Subjects Enrolled to Date: N/A

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an *FDA-awarded IND*. *(May be continued on a separate* sheet, and designated as "(14)e".

(15) Study Objective:

a. To evaluate the effectiveness of low dosage levels of Isotretinoin in reducing the incidence of basal cell carcinomas in high risk population.

b. To examine possible side-effects associated with long term asministration of low doses of Isotretinoin.

(16). TECHNICAL APPROACH: This will be a double-blind study with participants randomly assigned to active drug (Isotretinoin) or placebo. Patients will take their assigned drug or placebo for three years and will be followed for an additional two years after discontinuing medication. Compliance, side-effects and appearance of new basal cell carcinomas will be noted.

(17). Study has not yet started pending hiring of Nurse Specialist. This has now been accomplished and it is expected that the study will commence in October 1984.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/106D (3) Status: Ongoing

(4) Title: Efficacy of Weekly Pulse Methotrexate in the Treatment of Rheumatoid Arthritis: A double blind crossover study

(5) Start Date: 1983	(6) Est Compl Date: 1987
(7) Principal Investigator: Peter A. Andersen, MD, MAJ, MC Sterling G. West, MD, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators: Robert G. Claypool, MD, COL, MC Richard C. Welton, MD, MAJ, MC Charles S. Via, MD, MAJ, MC
(11) Key Words: RA Methotrexate	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

c. Number of Subjects Enrolled During Reporting Period: 13

d. Total Number of Subjects Enrolled to Date: 13

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". none

(15) Study Objective: Part I - Evaluate effectiveness of weekly pulse MTX to control activity of RA in patients who have failed therapy with gold shots and D-Penicillamine. Part II - Evaluate the potential of weekly pulse MTX to halt or decrease the progress of destructive changes of articular cartilage and bone. Part III - Evaluate the potential for toxicity of weekly pulse MTX.

(16) Technical Approach: Part I - 27 week double blind crossover study of MTX vs placebo comparing joint counts, functional tests, laboratory parameters and subjective scores. Part II - Blinded comparison of pretreatment and q6month sequential roentenographs of involved joints. Part III - Evaluation of biochemical liver function studies and comparison with sequential changes on liver biopsy.

(17) Progress: During the past year there have been 15 patients enrolled in the study, nine at Fitzsimons and six at Brooke Army Medical Center; 13 have completed the study 1 April 1984. Currently these data are being evaluated and compiled on the patients who have completed this study for presentation at the ARA National Meeting in June 1984.

Publications and Presentations: none

DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &
HSPA-I Ltr,
8 July 1982

(1) Date: FY 84 (2) Protocol WU Nr.: 83/103(3) Status: Ongoing

(4) Title:

Role of Vitamin K Deficiency in Bone Metabolism

(5) Start Date: 1983	(6) Est Compl Date: Maybe 1985
(7) Principal Investigator Vasundhara G. Iyengar	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Hematology/Oncology	(10) Assoc Investigators:
(11) Key Words: Vitamin K Coumadin Osteoporosis Osteopenia	
(12) Accumulate MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Feb 83 b. Review Results: on-going

c. Number of subjects enrolled during reporting period: 8

d. Total number of subjects enrolled to date: 8

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: Ø

(Continue on a separate sheet, designating this continuation as (14)c.)

(15) Study Objective:

To find out in a cross sectional study design, if Coumadin in long term therapeutic doses can induce significant osteopenia or osteoporosis.

(16) Technical Approach:

Obtain one time bone density measurements of patients on Coumadin and control population and comparing results to see if there is significant difference between the two populations.

(17) Progress:

No progress has been made since last report due to my involvement with another research project at the University of Colorado.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/102 (3) Status: ongoing

(4) Title: A survey of extrachromosomal elements of Legionella pneumophilia serotype 1, from environmental and clinical isolates.

(5) Start Date: February 1983	(6) Est Compl Date: December 1984
(7) Principal Investigator: Steven M. Opal, MD, MAJ, MC Carol Ciesielski, MD, Infect. Disease Svc, CU Med Center	(8) Facility: FAMC
(9) Dept/Svc: DOM, Infectious Dis.	(10) Assoc Investigators: Ms. Pari Morse, GS-9, Microbiologist Paul G. Engelkirk, LTC, MSC, PhD
(11) Key Words: Legionella pneumophilia Serotype I, virulence plasmids	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA
c. Number of Subjects Enrolled During Reporting Period: none
d. Total Number of Subjects Enrolled to Date: none
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None.

(15) Study Objective:
The objective of this protocol is to isolate the plasmid DNA of several environmental and clinical isolates of L. pneumophilia, and to compare their plasmid profiles.

(16) Technical Approach:
Legionella pneumophilia plasmid DNA will be prepared by rapid alkaline precipitation method and analyzed by agarose gel electrophoresis.

(17) Progress:
The plasmid DNA samples are being isolated from Legionella pneumophilia at the present time. Delays in performing agarose gell electrophoresis preps owing to lack of DNA transilluminator (now available).

Publications and Presentations: none

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/101 (3) Status: Ongoing

(4) Title: Genetics of Exfoliatin B production from clinical isolates of Staphylococcus aureus which produced staphylococcal scalded skin syndrome.

(5) Start Date: February 1983	(6) Est Compl Date: June 1985
(7) Principal Investigator: Steven M. Opal, MD, MAJ, MC. Allan S. Cross, MD, LTC, MC, WRAIR, Washington, D.C.	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Infectious Dis	(10) Assoc Investigators: Ms. Pari L. Morse, GS-9, Microbiologist, FAMC. Paul G. Engelkirk, LTC, MSC, PhD, FAMC.
(11) Key Words: Exfoliatin B, Staphylococcal scalded skin syndrome, Staphylococcal plasmids.	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period: Not applicable.

d. Total Number of Subjects Enrolled to Date: Not applicable.

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

Not applicable.

(15) Study Objective:

The objective of this study is to isolate plasmid DNA responsible for the production of exfoliatin B production in Staphylococcus aureus strains. The restriction endonuclease digestion pattern of this isolate will be compared with that of other exfoliatin B producers as well as reference strain from the CDC.

(16) Technical Approach:

Staphylococcal plasmid DNA was isolated by cleared lysis technique and by cesium chloride ultracentrifugation density gradients. The isolated plasmid DNA was then run on agarose gel eletrophoresis for molecular weight sizing. The endonuclease digestion pattern will then be obtained by digesting this plasmid with restriction endonuclease enzymes.

(17) Progress:

The initial plasmid isolation and characterization of the plasmid molecular weight on agarose gel has been accomplished. This information was submitted for publication without the restriction endonuclease digestion since the co-authors of this paper felt that it should be rapidly published. However, the reviewer in General Infectious Disease felt that restriction endonulcease digestion pattern was required prior to publication. Therefore, this work will be accomplished in this next fiscal year. The protocol is therefore ongoing, and the remaining studies that need to be performed are the restriction endonulcease digest patterns. The aforementioned progress was made during fiscal year 1984.

Publications and presentations: None.

DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &
HSPA-I Ltr,
8 July 1982

(1) Date: FY 84 (2) Protocol WU Nr.:83/100 (3) Status: COMPLETED

(4) Title: A survey of bacterial virulence factors in E. coli, and their significance in the pathogenesis of gram negative bacillary infections in man.

(5) Start Date: 1 Feb 83	(6) Est Compl Date: Jan 84
(7) Principal Investigator Opal, Steven M. MD,MAJ,MC Cross, Alan S. MD,LTC,MC Gemski, Peter PhD	(8) Facility: FAMC
(9) Dept/Svc: Med/Inf Dis	(10) Assoc Investigators: Morse, Pari L. Engelkirk, Paul G. LTC, MSC
(11) Key Words:E. coli virulence factors gram-negitive bacillary infections	
(12) Accumulate MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:_____ b. Review Results:_____

c. Number of subjects enrolled during reporting period:_____

d. Total number of subjects enrolled to date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.:_____

(Continue on a separate sheet, designating this continuation as (14)c.)

(15) Study Objective: The objectives are three-fold: 1) to determine the frequency with which certain virulence factors are found in bacteremic E. coli isolates; 2) to compare this frequency with that found in urinary and stool isolates from normal individuals; and 3) to determine the relationship between these virulence factors and host response to infection.

(16) Technical Approach:

Fifty random stool isolates were obtained from normal patients and compared with over 100 blood and urinary isolates for the presence of virulence factors.

(17) Progress: The K, and rough phenotype, hemolysin production, serum sensitivity, iron uptakes, colicin production, hemagglutinin phenotype, and plasmid profile for all 50 stool isolates as well as urinary and blood isolates has been completed. The final statistical analysis and preparation of the manuscript is in progress.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/116 (3) Status: Ongoing

(4) Title: ASSESSMENT OF REGIONAL WALL MOTION ABNORMALITIES BY RADIONUCLIDE ANGIOGRAPHY; EFFECT OF SUBLINGUAL NITROGLYCERIN

(5) Start Date: 1982	(6) Est Compl Date:
(7) Principal Investigator: STEVEN J. RAIBLE MD MAJ MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Cardiology	(10) Assoc Investigators: RICHARD C. DAVIS JR MD PhD LTC MC JOHN JACKSON, MD MAJ MC PETER W. BLUE MD LTC MC
(11) Key Words: RVG nitroglycerin introglycerin angiography	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

0

(15) Study Objective: This study is designed to analyze the sensitivity and specificity of radionuclide angiography in assessing segmental wall motion abnormalities after nitroglycerin administration and after coronary artery bypass grafting.

(16) Technical Approach: Forty patients with stable angina and atherosclerotic heart disease involving one or more vessels with a wall motion abnormality documented by cardiac catheterization within six months prior to gated radionuclide ventriculography (RVG) will be studied. Patients will be between the ages of 30 and 65. No study candidate will have had a prior transmural myocardial infarction or have aortic or mitral valvular heart disease. Those patients undergoing coronary artery bypass grafting will have repeat RVG approximately 10 days after surgery. All patients will be tested in a basal fasting state and will have all nitroglycerin preparations withheld for 24 hours prior to the study.

(17) Progress: No accountable progress has been made on this study due to technical problems, finding suitable patients and arranging suitable time with physicians and technicians.

PUBLICATIONS AND PRESENTATIONS: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/115 (3) Status: Ongoing

(4) Title: SERIAL TWO-DIMENSIONAL ECHOCARDIOGRAPHIC EVALUATION OF ACUTE ANTERIOR MYOCARDIAL INFARCTIONS FOR DETECTION OF LEFT VENTRICULAR THROMBI

(5) Start Date: November 1982	(6) Est Compl Date:
(7) Principal Investigator: GUY N. PIEGARI JR MD MAJ MC	(8) Facility: FAMC
(9) Dept/Svc: MEDICINE/CARDIOLOGY	(10) Assoc Investigators: RICHARD C. DAVIS JR MD PhD LTC MC HARRY M. THOMAS JR MD COL MC
(11) Key Words: 2-D echocardiography left ventricular thrombus	
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	(13) Est Accum OMA Cost:*

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

NA

(15) Study Objective: Assess incidence of mural thrombi in patients with acute anterior MI.

(16) Technical Approach: Patients admitted to CCU with acute anterior MI receive serial 2-D echocardiogram over 10-day period.

(17) Progress: Since transfer of principal investigator, this study has been placed on hold status until availability of another principal investigator to continue the study.

PUBLICATIONS AND PRESENTATIONS: None.

DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &
HSPA-I Ltr,
8 July 1982

(1) Date: FY (2) Protocol WU Nr.: 83/116 (3) Status: Terminated

(4) Title:

Intraarterial Cisplatin Therapy for Unresectable or Recurrent Adenocarcinoma of the Pancreas. A Phase II Study.

(5) Start Date: 1 April 1983 (6). Est Compl Date: 7 August 1984

(7) Principal Investigator (8) Facility: FAMC
Nicholas J. DiBella, M.D.

Hematology/Oncology Svc

(9) Dept/Svc: Dept of Medicine (10) Assoc Investigators:

(11) Key Words:

(12) Accumulate MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of subjects enrolled during reporting period: 2

d. Total number of subjects enrolled to date: 2

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet, designating this continuation as (14)e.)

(15) Study Objective:

To determine whether intraarterial cisplatin can be used for local control of adenocarcinoma of the pancreas.

(16) Technical Approach:

Intraarterial cisplatin was infused via arterial catheter at 4 week intervals using CT scan and other objective measurements of tumor activity to determine whether the tumor was responding.

(17) Progress:

One patient received nine courses of intraarterial cisplatin with no change in the CT scan appearance of the pancreatic mass. There was a fall in the renal function to a creatinine clearance of approximately 55 cc/min so that chemotherapy was discontinued. CT directed biopsy of the mass revealed only fibrosis and the patient continues to do well. He is being followed at regular intervals with repeat CT scans and liver function tests. He regained his weight and has remained basically asymptomatic during the course of treatment. The second patient had four doses of intraarterial cisplatin with some decrease in renal function but was taken off the study due to progression of disease within the liver. He has been switched to a new form of systemic chemotherapy. Both patients experienced mild to

DETAIL SUMMARY SHEET

Continuation of (17)e

moderate nausea and vomiting which was controlled with metoclopramide, diphenhydramine and dexamethasone. These side effects and the decrease in renal function were both expected from use of intraarterial cisplatin.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/117 (3) Status: Ongoing

(4) Title:
The Role of Altered Arachidonic Acid Metabolism in the Atherogenesis and Bleeding Tendency of Hypothyroidism, and the Response of This System to Thyroid Hormone Replacement

(5) Start Date: 1 Aug 83

(6) Est Compl Date: 1 Aug 85

(7) Principal Investigator:
Gerald S. Kidd, MD, LTC, MC
Robert J. Sjoberg, MD, CPT, MC
T. P. O'Barr, Ph.D., DAC
Ellen Swanson, DAC

(8) Facility: FAMC

(9) Dept/Svc: Medicine/Endocrine

(10) Investigators: (Cont)
Principal
Donald Corby, MD, COL, MC
Fred D. Hofeldt, MD, COL, MC (Ret)

(11) Key Words:
arachidonic acid metabolism
hypothyroidism
PGI_3, Tx A_2, B_2

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: Approx 200 Sprague-Dawley rats

d. Total Number of Subjects Enrolled to Date: Same

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A

(15) Study Objective:

To evaluate the effects of hypothyroidism or rat platelet thromboxane A_2 (TxA_2) and aortic ring prostacycline by measuring thromboxane B_2 (TxB_2) and 6-ketoprostaglandin F1α (6K-PGF1α), respectively in hypothyroid Sprague-Dawley rats. Second, to determine the effects of treatment on the same parameters with "low and high" dose levothyroxine.

(16) Technical Approach:

Rats made hypothyroid and controls were sacrificed at various intervals after collecting blood, counting platelets and aggregating platelets. TxB_2 was measured after aggregation by specific RIA segments of aorta were removed, sliced and incubated. Incubate solutions (at various times) were removed for the measurement of 6K-PGF1α by RIA. Similar procedures were performed on hypothyroid L-thyroxine treated rats.

(17) Progress:

During FY84, the majority of the study has been completed however more control data needs to be collected. Preliminary results have been presented on two occasions and accepted for presentation at another meeting. Approximately 200 rats have been studied (all groups) and this data has been evaluated. Several minor aspects related to treatment and the effects of aging on the control animals needs further work.

PRESENTATIONS FOR FY 84 Annual Progress Report Proto No 83/117

SERVICE Endocrinology/Biochemistry DEPARTMENT Medicine/Clinical Investigation

(1) Sjoberg, R.J., Kidd, G.S., Swanson, E., O'Barr, T.P., Corby, D., and Hofeldt, F.D.: Platelet and Vessel Wall Arachidonic Acid Metabolism in Hypothyroidism. Presented: ACP Associated Meeting, Denver, CO, 1984.

(2) Sjoberg, R.J., Kidd, G.S., Swanson, E., O'Barr, T.P., Hofeldt, F.D.. Platelet Thromboxane and Arterial Wall Prostacyclin Generation in Hypothyroid Rats and Their Response to Thyroid Hormone Replacement. Presented: Hugh Mahon Lectureship Award, Fitzsimons Army Medical Center, Aurora, CO, 1984.

(3) Sjoberg, R.J., Kidd, G.S., Swanson, E., O'Barr, T.P., Wetherill, S., Corby, D., and Hofeldt, F.D.: Thromboxane and Prostacyclin Generation in Hypothyroidism. Accepted for Presentation, Eastern Section, AFCR, Philadelphia, PA, 18 Oct 84.

PUBLICATIONS: NONE

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/119 (3) Status: Ongoing

(4) Title: Sardoidosis: Varying Lymphocyte Concentration in Sequential Bronchoalveolar Lavage

(5) Start Date: Mar 1983	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Clarence Hendrix, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc: Pulmonary/Medicine	(10) Assoc Investigators: David Thomas MAJ, MC Talmadge King MD
(11) Key Words: BronchoAlveolar Lavage Sarcoidosis Alveolitis	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 10

d. Total Number of Subjects Enrolled to Date: 10

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To establish the effect, if any, of sequential bronchoalveolar lavage on the proportion of lymphcytes recovered.

(16) Technical Approach: The bronchoscope is wedged in a peripheral location and aliquots of saline, 30 ml, injected into a segmental bronchus. Each aliquot is recovered and analyzed. A total of 300 ml are injected. From analysis of each aliquot, correlation between cell population and disease activity will be determined.

(17) Progress: A definite relationship between the amount of saline instilled and the proportion of lymphocytes recovered has been established. Washings with only 30 ml of saline are misleading because of the high proportion of neutrophiles isolated. If the first 30 ml aliquot is discarded and the next threee aliquots collected more consistent data is collected. Collection of lavage fluid in excess of 90 ml has been found to yield little additional information.

Publications: None

Presentations: Hendrix, C., Bronchoalveolar Lavage Analysis in Sarcoidosis. Presented: American College of Physicians Associates Meeting, Denver, CO March, 1984.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/120 (3) Status: Ongoing

(4) Title: Correlation of Renal Concentrating Ability With Hemoglobin S Concentration in Healthy Military Personnel With Sickle Cell Trait: A Clinical Study

(5) Start Date: 1984 (6) Est Compl Date:

(7) Principal Investigator:
John R. Hess,MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc:Hematology/MED

(10) Assoc Investigators:
Gary Rombert, LTC, MC, USAF
Richard Artim, MAJ, MC, USAF

(11) Key Words:
sickle cell
hemoglobin S

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Sep 84 b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 11

d. Total Number of Subjects Enrolled to Date: 11

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded *IND*. (May be continued on a separate sheet, and designated as "(14)e". none

(15) Study Objective: To crrelate renal concentrating ability with hemoglobin S concentration in individuals with sickle cell trait in the military age range.

(16) Technical Approach: Patient selection at the United States Air Force Academy with sickle cell trait and normal renal function as documented by a normal urine analysis and a serum creatinine concentration of 1.2 or less at prior screening would be accepted as volunteers for this study after giving informed consent. There are 23 such cadets at this time. Cadets would be instructed to abstain from drinking water after 1900 hr the day before the study and to report at 0700 hr to the study area. Hourly urine samples would be collected for six samples and measured for osmolality and urine volume and two blood samples would be drawn one at the beginning and one at the end of the urine collection period and measured for osmolality and electrolytes, glucose, BUN and creatinine. The six osmolalities and volumes for each individual would be plotted to see that they approach a maximum concentration ability.

(17) Progress: Eleven patients have been entered in the study thus far with no problems encountered. Correlation has been demonstrated, we will continue to collect data.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/121 (3) Status: ongoing

(4) Title: Expiratory Spirometry/Lung Compartment Ratios for Assessment of Pulmonary Impairment

(5) Start Date: Aug 83	(6) Est Compl Date: April 1986
(7) Principal Investigator: John D. Olsen, M.D. CPT, MC	(8) Facility: FAMC
(9) Dept/Svc:Pulmonary/DOM	(10) Assoc Investigators: Michael E. Perry, M.D. COL, MC
(11) Key Words: Spirometry Ratios	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period: 26
d. Total Number of Subjects Enrolled to Date: 26
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". none

(15) Study Objective:

(1) Define normal ratios for $FEV_{(1)}$/TLC; $FEV_{(1)}$/RV; $FEV_{(1)}$/FRC.

(2) Determine if these simple ratios are a better mediator of obstructive lung impairment than the $FEV_{(1)}$/FVC

(16) Technical Approach:
An estimated 100 subjects to be enrolled and will undergo routing spirometry, body plethysmography and a minimal exertion on a treadmill at 0 grade and 2 mph for 4 min measuring minute vetilation ratios will be generated from this data and statistically analyzed.

(17) Progress:
Twenty-six patient and controls have been accumulated from Aug 83 to current (Oct 84). This number is too few to make an analysis of the results.

Pulbications and Presentations: None

DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &
HSPA-I Ltr,
8 July 1982

(1) Date: FY 30 SEP 84 (2) Protocol WU Nr.: 83/122 (3) Status: ONGOING

(4) Title:
The Role of Food Allergy in the Pathogenesis of Migraine Headaches

(5) Start Date: SEP 83 (6) Est Compl Date: JUN 85

(7) Principal Investigator (8) Facility: FAMC

Harold S. Nelson, M.D., Col., MC

(9) Dept/Svc: MC Allergy Imm.

(10) Assoc Investigators:
Brian T. Miller, DO, Cpt., MC
Wesley Stafford, MD, MAJ., MC
Thurman T. Vaughan, MD, CPT., MC

(11) Key Words:
Migraine headache,
Food Allergy,
Prostaglandins

(12) Accumulate MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:
c. Number of subjects enrolled during reporting period:
d. Total number of subjects enrolled to date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.:

(Continue on a separate sheet, designating this continuation as (14)e.)

(15) Study Objective: In this study the value of skin testing to a battery of food allergens will be determined in directing therapy and defining a diet which will cause a decreased frequency of migraine headaches in affected patients.

(16) Technical Approach:
(See continuation sheet.)

(17) Progress:
(See continuation sheet.)

Incl 1

16. In this study, approximately 100 patients will be randomly referred from the Neurology Clinic who have at least three migraine headaches a month. Those patients will on a regular diet, keep dietary records and be taken off any chronic medications over a 30-day period. They will then undergo skin testing to 83 common foods and be placed on an allergy elimination diet for 30 days. If there is a reduction in the frequency of headaches, they will undergo an open challenge and if that is positive they will undergo double-blind challenges.

17. Progress: At the present time 24 people have been enrolled in the study. One patient has completed the full study including double-blind challenges and is headache-free when avoiding nitrates, benzoates, and wheat. This was confirmed six out of six times by double blind challenges. Six patients have completed both the elimination diet and the regular diet trial and are ready for entry into the open challenges. The remaining patients are currently undergoing Phase I in which they keep dietary records while stopping their chronic medications. In addition, we are in the act of obtaining a number of charcoal capsules filled with either dextros as a placebo or the appropriate foods for challenges in an effort to speed up the double-blind challenges.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/123 (3) Status: Ongoing

(4) Title: In Vitro Testing of Cryopreserved Parathyroid Tissue: Functional Viability and Replicative Capacity After Using a "Simplified" Freezing Technique

(5) Start Date: October 1983	(6) Est Compl Date:
(7) Principal Investigator: William A. Collazo, CPT, Mc Gerald S. Kidd, II, LTC, MC Albert McCullen, CPT, VC	(8) Facility: FAMC
(9) Dept/Svc: Endo/Medicine	(10) Assoc Investigators: Don Mercill, DAC Les Kramer, SP5
(11) Key Words: crypreserved parathyroid	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: Dog parathyroid tissue will be cryopreserved for various intervals using a "simplified" freezing technique which does not require a programmed freezer. The tissue is placed in tissue culture medium, 4°C, for two hours. The tissue is then transferred to chilled vials containing tissue culture medium, autologous serum, and DMSO and immediately placed in a freezer at -80°C. After 16 hours, the vials are directly transferred to a liquid nitrogen container for storage. Successful demonstration of adequate parathyroid function after cryopreservation will be the basis for attempting parathyroid autotransplantation of cryopreserved tissue in humans at our institution as well as a more general application at those institutions where only a "simplified" freezing technique could be accomplished.

(16) Technical Approach: Thawed tissue will be compared to fresh tissue using in vitro studies that measure functional viability and replicative capacity. Functional viability will be assessed by measuring the suppressibility of PTH from dispersed parathyroid cells in suspension when the calcium concentration in the solution is changed. Replicative capacity is the ability of a cell to incorporate nutrient materials for cell survival and replication will be assessed by measuring DNA, RNA and protein synthesis in the cryopreserved specimens.

(17) Progress: We have been able to isolate and remove parathyroid glands from a large dog without difficulty and have been able to run assays of PTH from both fresh and frozen specimens from one dog. The only problem encountered is cell suspension technique needs reginement. We have been temporarily suspended from dog research until further notice.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/124 (3) Status: Ongoing

(4) Title: A Prospective Evaluation of Esophageal Changes in Patients Undergoing Esophageal Radiation

(5) Start Date: 27 April 84	(6) Est Compl Date: 31 December 85
(7) Principal Investigator: F. Moses, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc: Gastro/Med	(10) Assoc Investigators: M. Hurwitz, MAJ, MC P. Blue, LTC, MC R. Claypool, Col, MC
(11) Key Words: Radiation Esophagitis	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None.

(15) Study Objective:

To determine changes prospectively in structure and function of the esophagus while undergoing radiation as an innocent bystander by means of a standardized questionaire, upper panendoscopy with viral and fungal culture, esophageal radionuclide scan, 24 hour pH monitor and esophageal motility.

(16) Technical Approach:

Patients entered into the protocol undergo the above listed tests (see study objective) in standard medical fashion at inception of radiation, 4 weeks into radiation, and 4 months after start of radiation.

(17) Progress:

Since the start of the protocol at the date as listed above, two patients have been entered into the protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/125 (3) Status: ongoing

(4) Title:
Carbon Dioxide Retention with PEEP during High Frequency Jet Ventilation

(5) Start Date: May 1984	(6) Est Compl Date: May 1985
(7) Principal Investigator: Keith Wolfe Capt MC Michael Perry COL MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Pulmonary	(10) Assoc Investigators:
(11) Key Words: Dead Space High Frequency Ventilation Carbon Dioxide	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 6 animals

d. Total Number of Subjects Enrolled to Date: 6 Animals

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A

(15) Study Objective: To ascertain if changes in CO_2 retention during high frequcny jet ventilation are due solely to changes in tidal volume or whether some other factor such as dead space may be a factor.

Technical Approach

(16) Animals will be studied at a constant frequcny and I:E ratio, while varying the driving pressure to maintain a constant Tidal volume. Increases in CPAP (or PEEP) will be made and the corresponding changes in CO_2 retention observed.

(17) Progress: A definite relationship between CPAP and CO_2 retention, independant of tidal volume was established at frequencies of 200/min. This may or may not also be the case for lower frequencies if we had sighed the dogs and ensured that the animals did not develope atelectasis at lower frequencies as we did for the higher frequencies. The time course of CO_2 retention was surprising, and it usually required at least an hour for this to fully develop. A modification to the protocol was requested and approved to study the possible effect of cardiac output which drops with the added CPAP. This possiblilty is being currently studied.

Presentations: Wolfe, G.K., Perry, M.E.: CPAP-Induced Carbon Dioxide Retention During High Frequency Jet Ventilation. To be presented: Carl W. Tempel Pulmonary Disease Symposium, San Francisco, CA, October 1984.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/126 (3) Status: Ongoing

(4) Title: The Role of Altered Prostaglandin Synthesis in the Impaired Water Excretion and Abnormal Renin-Aldosterone Axis of Hypothyroidism

(5) Start Date: August 1983	(6) Est Compl Date: August 1985
(7) Principal Investigator: Robert J. Sjoberg, MD, CPT, MC Gerald S. Kidd, MD, LTC, MC Thomas P. O'Barr, Ph.D. Fred D. Hofeldt, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Endocrine	(10) Assoc Investigators:
(11) Key Words: prostaglandin synthesis water metabolism hypothyroidism	None.
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective of this study is to determine in an indirect manner, i.e. with prostaglandin synthesis inhibition, if the abnormal suppressibility of vasopressin and/or altered renal sensitivity to vasopressin seen in hypothyroid patients is caused by altered prostaglandin levels. This will be done by measuring serum vasopressin levels and urinary water excretion in response to a water load, as well as the renal response to exogenous vasopressin, in hypothyroid patients with and without prostaglandin synthesis inhibition, both before and after treatment with thyroid hormone to the point of euthyroidism. In the same way, the influence of altered prostaglandin levels on the renin-aldosterone axis of hypothyroidism will be studied by measuring plasma renin activity and aldosterone levels in these patients while in a relatively volume deplete state, that is before the water loading is performed.

Altered renal prostaglandin synthesis in hypothyroidism will also be assessed directly by measuring urinary PGE-2 excretion in the hypothyroid and euthyroid states. (Urinary PGE-2 excretion is thought to reflect primarily renal PGE-2 production.)

(16) Technical Approach:

By measuring urinary prostaglandin E and water loading responses in hypothyroid patients before and after indomethacin administration as well as measuring plasma, aldosterone, and plasma renin activity we will evaluate the effects of prostaglandin synthesis inhibition on water metabolism.

CONTINUATION SHEET, FY 84 ANNUAL PROGRESS REPORT Proto No.: 84/110

(17) Progress:

This study is ongoing with initial screening of over 30 isolates of Campylobacter species. This data will be collated and serum resistance of these strains will be compared. Serum resistant plasma containing species will then be cured of their plasmids and retested to determine if any contribution serum resistance is carried on the extrachromosomal elements of Campylobacter species. This is reported for Fiscal Year 1984.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/110 (3) Status: On going

(4) Title: Survey of the extrachromosomal elements of Campylobacter species obtained from environmental and clinical isolates.

(5) Start Date: May 1984	(6) Est Compl Date: May 1985
(7) Principal Investigator: Steven M. Opal, MD, MAJ, MC Martin Blaser, MD, C, Inf Dis Service, VA Hospital.	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Infec. Diseas	(10) Assoc Investigators: Pari Morse, GS-9, Clinical Microbiologist, DCI.
(11) Key Words: Campylobacter; virulence factors; plasmids.	
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	(13) Est Accum OMA Cost:*

(14) a. Date, Latest HUC Review: None b. Review Results: Not applicable

c. Number of Subjects Enrolled During Reporting Period: Not applicable

d. Total Number of Subjects Enrolled to Date: Not applicable.

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective of this investigation is to study the extrachromosomal elements of Campylobacter species to determine their contribution to the virulence of these organisms. It has previously been demonstrated that virulence plasmids are present in virtually all the Enterobacteriaceae. These plasmids contribute to the resistance to the bacteriocidal effect of human serum. Campylobacter species C. fetus are uniformly serum resistant owing to a smooth LPS. Campylobacter jejuni are generally serum sensitive owing to rough LPS.

(16) Technical Approach:

Some relatively resistant Campylobacter species have been identified. These will be of great interest in studying the plasmid profile of these organisms to determine if any unique plasmid bands exist which might be contributing to the virulence of these isolates. It is anticipated that the finding of such plasmids will be confirmed by several methods of plasmid isolation and that plasmid curing experiments will be performed to remove the plasmids from the cytoplasma of these organisms. These cured organisms will then be retested to determine if a loss of serum resistance has occurred.

STUDY OBJECTIVE:

The objective of this project is designed to evaluate the value of two dimensional (2-D) echocardiographic analysis of exercise induced left ventricle wall motion abnormalities in the evaluation of patients with suspected ischemic heart disease. Pre and post exercise 2-D echocardiograms will be analyzed to identify exercise induced left ventricular wall motion abnormalities. These studies will be correlated with ST segment changes noted during exercise stress testing and to the findings at coronary cineangiography.

TECHNICAL APPROACH:

Twenty-five patients referred to FAMC for cardiac catheterization without evidence of a prior myocardial infarction will be enrolled in the study. The usual work up of these patients will be modified to include a 2-D echocardiogram at rest and after completing a treadmill stress test. The echocardiogram will be analyzed for changes in left ventricular wall motion that occur during exercise suggesting regional ischemic changes. These changes will be correlated with the data found at coronary cineangiography.

PROGRESS:

Since the start of this study in April 1984, 6 patients have been enrolled. In one patient the baseline echocardiogram was of technically poor quality and this patient was withdrawn from the study. Preliminary results of the remaining patients suggest a sensitivity and specificity of approximately 50%. These disappointingly poor results have been limited by the use of an echocardiography machine that yielded poor quality views, as well as a former echocardiogram technician that was less skillful at obtaining the appropriate views. By using the ATL echocardiography machine and our new technician, we are hopeful that these results will improve.

There have been no complications to date with the use of echocardiography added to treadmill stress testing.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/109 (3) Status: Ongoing

(4) Title: Two Dimensional Echocardiographic Evaluation of Exercise-Induced Wall Motion Abnormalities: Detection of Coronary Artery Disease

(5) Start Date: April 1984 (6) Est Compl Date: June 1985

(7) Principal Investigator:

William D. Bowden, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: Cardiology/ DOM

(10) Assoc Investigators:

COL H. Thomas, JR.

(11) Key Words:

Exercise echo
Ischemic Heart Disease

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

Please see next page

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/108 (3) Status: Ongoing

(4) Title: The effect of ultraviolet light (UVB) on the production of prostacyclin (PGI_2) by cultured human microvasculature endothelial cells.

(5) Start Date: 15 Dec 1983	(6) Est Compl Date: March 1985
(7) Principal Investigator: James E. Fitzpatrick MD Maj, MC	(8) Facility: FAMC
(9) Dept/Svc: Derm/DOM	(10) Assoc Investigators: Thomas P O' Barr PhD, DAC Ellen Swanson DAC Don Mercell DAC Chuck Ferris PhD, Capt, MSC
(11) Key Words: UVB, endothelial cells, prostacyclin	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: N/A b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: N/A

d. Total Number of Subjects Enrolled to Date: N/A

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A

(15) Study Objective: To determine if UVB in physiological doses will stimulate the release of prostacyclin from human endothelial cells.

(16) Technical approach: Endothelial cells will be cultured from adipose tissue and irradiated with various doses of UVB and Prostacyclin will be assayed by a RIA.

(17) Progress; Preiminary results have shown an increase of prostacyclin as anticipated but further studies will be needed to confirm this.

Publications: Bennion SD, Fitzpatrick JE, Harbell J, Swanson E, O'Barr T: The effect of UVB on 6-keto-PGF_{1a} production by cultured human endothelial cells. J. Invest Dermatol 82:428a, 1984.

Presentations: Bennion SD, Fitzpatrick JE, Harbell J, Swanson E, O'Barr T: The effect of UVB on 6-keto-PFG_{1a} production by cultured human endothelial cells. Presented to Society of Investigative Dermatology meeting in Washington DC, May 1984.

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(17) Progress:

This protocol is on going and will be completed as soon as the construction is finished on the third floor. It is anticipated that this will be complete by December 1984. Additional sampling of the construction area prior to reoccupying these areas for patient care will have to be conducted as well. A brief sampling and survey system will be employed after reoccupation of the newly construction areas to insure no additional cases of Aspergillus infections develop. This report is made for Fiscal Year 1984.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/107 (3) Status: On going

(4) Title: Survey of Aspergillus Contamination of the Environment During Hospital Renovation; and, the Efficacy of Infection Control Measures in Preventing Nosocomial Aspergillosis.

(5) Start Date: 30 Dec 83	(6) Est Compl Date: March 1985
(7) Principal Investigator: Steven M. Opal, MD, MAJ, MC. Arnold Asp, MD, CPT, MC, Linda J. Burton, MAJ, ANC.	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Inf Disease	(10) Assoc Investigators: Pari Morse, GS-9, Clinical Microbiologist, DCI. Philip Hammer, SP5, Infection Control Service. Preston B. Cannady, Jr., MD, COL, MC.
(11) Key Words: Aspergillus infection. Nosocomial infection.	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period: Not applicable

d. Total Number of Subjects Enrolled to Date: Not applicable

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective of this study is to determine the efficacy of Infection Control measures in preventing the spread of Aspergillus infections during hospital construction at FAMC. This institution has experienced a significant outbreak of nosocomial aspergillosis associated with hospital construction on the 4th floor. Construction is on going on the third floor and attempts have been made by the Infection Control Service to prevent similar episodes of invasive aspergillosis associated with this contruction project.

(16) Technical Approach:

By the use of physical barriers, external venting, high efficiency filters, and Copper-8-quinolinolate treatments, the incidence of nosocomial aspergillosis has decreased to no cases during the Infection Control project. A sampling of the hospital air has demonstrated a significant decrease in the amount of Aspergillus spores generated in patient care areas following the institution of Infection Control measures.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/106 (3) Status: Ongoing

(4) Title:

Respiratory Patterns in Hypogonadal Patients

(5) Start Date: Feb 84	(6) Est Compl Date: Feb 85
(7) Principal Investigator: Michael T. McDermott, MD, MAJ, MC Brenda Schneider, MD, Pulmonary Fellow, UCHSC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Endocrine	(10) Assoc Investigators: Gerald S. Kidd, MD, LTC, MC
(11) Key Words: hypogonadism testosterone sleep apnea	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Sep 84 b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 10

d. Total Number of Subjects Enrolled to Date: 10

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None.

(15) Study Objective:

to study the effect of sex hormones, testosterone and estrogen, on respiratory patterns and sleep apnea.

(16) Technical Approach:

Patients undergo hypoxic and hypercapneic ventilatory drive studies by measuring tidal volume and respiratory rate while breathing varying concentrations of oxygen and carbon dioxide and then undergo sleep studies under observation for the presence and frequency of sleep apnea. These studies are done in hypogonadal males 4 days and 4 weeks after shots of depotestosterone, and in postmenopausal females while on and after 4 weeks off Premarin and also once in hirsute females, who are compared with established normal controls.

(17) Progress:

Six male patients have completed both phases of the study. Sleep apnea and disordered respiratory patterns were much more prominent immediately after testosterone shots. Raw data is in the process of statistical analysis.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/103 (3) Status: Ongoing

(4) Title:

Gastric Inhibitory Polypeptide (GIP) in Various Disorders of Carbohydrate Metabolism

(5) Start Date: Feb 84	(6) Est Compl Date: Feb 88
(7) Principal Investigator: Michael T. McDermott, MD, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Endocrine	(10) Assoc Investigators: Gerald S. Kidd, MD, LTC, MC
(11) Key Words: gastric inhibitory polypeptide (GIP) hypoglycemia diabetes mellitus	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A

(15) Study Objective:

To measure GIP in states of altered carbohydrate metabolism such as diabetes mellitus and reactive hypoglycemia.

(16) Technical Approach:

Multiple serum samples on patients with diabetes mellitus and reactive hypoglycemia have been collected and stored according to previously approved protocols. In this study, we will use this stored serum to measure GIP.

(17) Progress:

No progress as of yet because the GIP RIA is still in the process of being established.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/102 (3) Status: Ongoing

(4) Title:

Development of a Radioimmunoassay for Gastric Inhibitory Polypeptides (GIP)

(5) Start Date: Feb 84	(6) Est Compl Date: Feb 86
(7) Principal Investigator: Michael T. McDermott, MD, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Endocrine	(10) Assoc Investigators: Gerald S. Kidd, MD, LTC, MC
(11) Key Words: radioimmunoassay gastric inhibitory polypeptide (GIP)	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A

(15) Study Objective:

To develop a radioimmunoassay to measure GIP.

(16) Technical Approach:

A RIA for GIP will be developed using established RIA techniques after purchase of GIP antibodies and purified GIP.

(17) Progress:

GIP antibodies and purified GIP have been obtained but thus far there has been difficulty iodinating the GIP. This will require further work.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/101 (3) Status: Ongoing

(4) Title: Antibiotic Therapy of Acute Exacerbations of Chronic Bronchitis: A controlled study using TMP/SMX.

(5) Start Date: Sept, 1984	(6) Est Compl Date: June, 1985
(7) Principal Investigator: Michael Witte Maj, MC Jimmy Gilbert Maj, MC Steven Opal Maj, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Pulmonary	(10) Assoc Investigators:
(11) Key Words: Trimethaprim/Sulfamethoxazole Chronic Bronchitis	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 1

d. Total Number of Subjects Enrolled to Date: 1

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded *IND*. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective:

This double-blind study was undertaken in an attempt to clarify whether a specific therapeutically useful antibiotic plays a significant role in in acute exacerbations of chronic bronchitis. The drug to be used is TMP/SMX. The patient population will include patients with documented moderate to severe bronchitis by clinical symptoms and pulmonary function tests who have acute exacerbations of their symptoms.

(16) Technical approach: Patients admitted with worsening pulmonary symptoms, who have no documented allergy to TMP/SMX undergo a bettery of tests as a baseline and a patient questionaire and physical exam and CXR. These are repeated on day 4 & 7 to see if there has been any improvement. On day 1 the patient is placed blindly on either a placebo or the study drug, and kept on it for seven days.

(17) Progress: One patient has been entered to date in fiscal year 1984 and, since the drug is unknown to the authors, it is not known whether the benefit seen is due to an antibiotic or placebo.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/100 (3) Status: Ongoing

(4) Title:
The Effect of Abnormal Thyroid States on the Metabolism of Theophylline and Methylprednisolone

(5) Start Date: Feb 84

(6) Est Compl Date: Jul 87

(7) Principal Investigator:
James S. Brown, MD, Maj, mc
Michael T. McDermott, MD, MAJ,MC

(8) Facility: FAMC

(9) Dept/Svc: Medicine/Endocrine

(10) Assoc Investigators:
Fred D. Hofeldt, MD
Stanley J.Szefler, MD, MAJ, MC
Harold S. Nelson, MD, COL, MC

(11) Key Words:
theophylline
methylprednisolone
hyperthyroidism
hypothyroidism

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 30 Sep 84 b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None.

(15) Study Objective:
To study the effects of hyperthyroidism and hypothyroidism on the metabolism of theophylline and methylprednisolone.

(16) Technical Approach:
Consenting hyperthyroid and hypothyroid patients will have a 12-hour intravenous infusion of theophylline or methylprednisolone or both (on separate days) and hourly blood levels of theophylline and/or methylprednisolone will be measured.

(17) Progress:
No patients yet enrolled.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/127 (3) Status: on-going

(4) Title: Double-blind controlled trial of individually polymerized grass pollens in the treatment of seasonal allergic rhinitis.

(5) Start Date: 1984	(6) Est Compl Date: 1985
(7) Principal Investigator: HS Nelson, MD, COL, MC	(8) Facility: FAMC Allergy-Immunology Clinic, FAMC, and Fort Carson Medical Activity
(9) Dept/Svc: Medicine/Allergy	(10) Assoc Investigators:
(11) Key Words: polymerized extract allergy immunotherapy	RW Weber, COL, MC BT Miller, CPT, MC ML Vandewalker, MAJ, MC
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 43

d. Total Number of Subjects Enrolled to Date: 43

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

none

(15) Study Objective: To assess the immunologic and symptomatic response to allergy immunotherapy with polymerized grass in a double-blind, placebo-controlled study.

(16) Technical Approach: Patients received over a period of 8 weeks eleven injections of polymerized grass extract or of a placebo containing histamine and caramelized sugar. The immunologic response is measured by titrated skin test, specific IgE and specific IgG performed before and after immunotherapy. Symptom scores are collected through the grass pollen season.

(17) Progress: Forty-three patients were randomized to placebo or active immunotherapy in the grass pollen season of 1984. It is now intended that those who receive the placebo will receive the active drug and for the grass pollen season of 1985, the effect of booster injections will be studied.

Publications and Presentations: None

CONTINUATION SHEET, FY 84 ANNUAL PROGRESS REPORT Proto No.: 83/126

(17) Progress:

No patients have been entered in this study during the past year because of conflicting priorities in our unit. However, we anticipate studying five patients during the coming fiscal year.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/111 (3) Status: Ongoing

(4) Title: Incidence of Bacteremia Following Transbronchial Needle Aspiration and Fiberoptic Bronchoscopy.

(5) Start Date: May, 1984

(6) Est Compl Date: June, 1984

(7) Principal Investigator:
Dr. Michael Witte D.O. MAJ, MC
Dr. Jimmy Gilbert M.D. MAJ, MC
Dr. Steven Opal M.D. MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Medicine/Pulmonary

(10) Assoc Investigators:
Dr. Jerry Pluss D.O. CPT, MC
Dr. David Thomas M.D. MAJ, MC
Dr. John Olsen M.D. MAJ, MC

(11) Key Words:
TBNA
BACTEREMIA

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 22

d. Total Number of Subjects Enrolled to Date: 22

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14) e".

None

(15) Study Objective:

The objective of the study is to determine the incidence of bacteremia following transbronchial needle aspiration. This is a procedure which is gaining widespread use in diagnostic pulmonology as applied to lung neoplasms. The study is prospective. The current AHA recommendations are to not prophylax high risk patients for infective endocarditis when undergoing fiberoptic flexible bronchoscopy. This recommendation will need to be reassessed based on the findings of this study.

(16) The patients undergoing TBNA have blood cultures drawn 5 minutes, 30 minutes, and any time in the 24 hours after the procedure if the oral temperature is 100.4° F. These cultures are handled in the microbiology division as per their routine protocol.

(17) Progress: To date, 22 TBNA's have been completed on 20 patients. There has been no incidences of bacteremia at any time in the 24 hours following the procedure. There have been four incidences of fever, two of which were accounted for by the diagnosis of pneumonia. A larger number of patients will be seen in fiscal year 1985. This is data from fiscal year 1984.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/112 (3) Status: Ongoing

(4) Title:
Proteinuria and Congestive Heart Failure

(5) Start Date: June 84	(6) Est Compl Date: July 85
(7) Principal Investigator: JAMES A. HASBARGEN, MD MAJ, M.C. RICHARD F. KUCERA, M.D.	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words: proteinuria congestive heart failure	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 5
d. Total Number of Subjects Enrolled to Date: 5
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: Proteinuria generally connotates significant renal disease. It is normally investigated thoroughly up to and including renal biopsy. Congestive heart failure has been stated to be a cause of proteinuria in the past. This is not well substantiated in the literature and whether it improves with treatment, is unanswered. Consequently, it is important to know whether there is a true cause and effect relationship with congestive heart failure and proteinuria, and whether the proteinuria resolves with resolution of congestive heart failure. This study, therefore, will seek to determine the incidence of proteinuria in patients presenting with congestive heart failure, and whether the proteinuria resolves with resolution of congestive heart failure.

(16) TECHNICAL APPROACH: The patient selected for the patient study will be over 18 years of age, and have no past history of renal disease. The patients will have the clinical diagnosis of congestive heart failure. The physician and the patient must be willing to submit to a urine collection and follow up if the patient is found to have proteinuria. The following historical, physical exam and laboratory criteria must be met prior to the patient's entry into the study. Patient must have a negative history of renal disease with the exception of uncomplicated urinary tract infections. A comprehensive drug history will also be obtained from the patients. The patients will have a clinical diagnosis of congestive heart failure as ascertained using the following cirteria: history of shortness of breath, PND, edema, prior documentation of congestive heart failure physical exam findings to include neck vein distention, hepatojugular reflux, S_3, and cardiomegaly and edema. Radiologic findings to include cardiomegaly, cephalization of flow, and curly B-lines. Additional diagnostic studies to document congestive heart failure may be utilized at the discretion of the attending physician to include: echocardiography, radionuclide cardiography and cardiac catheterization. The patients will have complete urinalysis performed. They will have a spot urinalysis done to examine both creatinine and protein concentration utilizing that plus the serum creatinine to be able to

calculate a 24 hour urinary collection. Patients manifesting proteinuria and/or congestive heart failure. Patients whom are discharged prior to the resolution of the proteinuria will be followed as outpatients at the discretion of their attending physician.

(17) Progress: The study is in the preliminary stages. Five patients are enrolled at the current time. No data analysis has been done as yet.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/113 (3) Status: on-going

(4) Title: Functional assay to determine shelflife of methacholine and atropine methylnitrate solutions

(5) Start Date: 1984	(6) Est Compl Date: 1984
(7) Principal Investigator: W. Ronald Tipton, MD, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Allergy	(10) Assoc Investigators: Robert A. Ledoux, BS Ray Vaughan, MD, CPT, MC
(11) Key Words: methacholine atropine methylnitrate	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

NA

(15) Study Objective: To determine the duration of potency in solution of two medications used in the diagnosis and treatment of obstructive pulmonary disease.

(16) Technical Approach: Using the guinea pig trachea model, the shelflife of methacholine up to one year after mixture will be compared to freshly made solution. Likewise, inhibition of a methacholine contraction by atropine methylnitrate also insolution having been mixed for periods up to one year will be used. When compared to fresh solutions, these determinations should give an indication of the functional shelflife of these two drugs.

(17) Progress: Thus far the medications are being accumulated, and animals will be ordered shortly to do these assays.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/114 (3) Status: on-going

(4) Title: The relative development of subsensitivity to the bronchodilator and musculoskeletal side effects of specific beta-2 adrenergic agonists.

(5) Start Date: 1984	(6) Est Compl Date: 1985
(7) Principal Investigator: HS Nelson, MD, COL, MC	(8) Facility: FAMC Allergy-Immunology Clinic
(9) Dept/Svc: Medicine/Allergy	(10) Assoc Investigators: Westley Stafford, MAJ, MC
(11) Key Words: beta adrenergic agonists subsensitivity	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

none

(15) Study Objective: To compare the development of subsensitivity with chronic administration to terbutaline and albuterol using measurements of bronchodilator effect and tremor.

(16) Technical Approach: Patients will receive oral albuterol, oral terbutaline, or placebo on three separate days and the bronchodilator response and tremor response will be measured. They will then receive in a crossover fashion 3 weeks of oral albuterol and 3 weeks of oral terbutaline.At the end of each 3 week treatment period the bronchodilator and tremor response to the drug that they had been receiving and to placebo will be measured.

(17) Progress: Approval of this protocol was not received until 24Aug84; therefore, study has not yet been initiated.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/115 (3) Status: Ongoing

(4) Title:

Heterotransplantation of Basal Cell Carcinomas to Nude Mice.

(5) Start Date: Aug 84	(6) Est Compl Date: Jul 86
(7) Principal Investigator: Ronald E. Grimwood, M.D. LTC,MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Dermatology	(10) Assoc Investigators: Charles Ferris, PhD, CPT, MSC J. Clark Huff, M.D.
(11) Key Words: Carcinoma Basal cell Nude mice	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: N/A

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

To develop an in-vivo model of human basal cell carcinoma in the athymic mouse.

(16).TECHNICAL APPROACH: Basal cell carcinoma tissue obtained from excess tissue obtained from Moh's surgery is transplanted to a subcutaneous pocket created by a linear incision on the abdomen of the nude mouse. The mouse will have been splenectomized and transplantation is followed by weekly intraperitoneal injections of antilymphocyte serum. Tumor weight is taken before implantation and measurements of tumor size taken at weekly intervals. Autoradiography and immunofluorescent studies are performed at the time of tumor harvest as well as routine histology and tumor weight.

(17). PROGRESS: To date we have successfully transplanted 15 tumors which maintain the histology and protein products of the originally transplanted tumor. We are now actively defining the growth perameters of these tumors but do not have completed data yet.

PUBLICATIONS/PRESENTATIONS:

a. Grimwood RE, Johnson CA, Ferris CF, Mercill DB, Mellette JR, Huff JC: Transplantation of Human Basal Cell Carcinomas in Athymic Mice. Accepted for publication in Cancer, 1984.

b. Grimwood RE, Harbel J, Clark RAF: Fibronectin in Basal Cell Epitheliomas: Sources and Significance. Journal of Investigative Derm 82: 145-149, 1984.

CONTINUATION SHEET, FY 84 ANNUAL PROGRESS REPORT Proto No.: 84/115

PRESENTATION:

a. Grimwood RE, Johnson CA, Kramer LC, Mercill DB and Huff JC: Heterotransplantation of Human Basal Cell Epitheliomas in Nude Mice. Presented at the SID Meeting in Washington, DC, May 84.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/116 EU(3) Status: Terminated

(4) Title: EU: Carnitine

(5) Start Date: 1984	(6) Est Compl Date: N/A
(7) Principal Investigator: Daniel L. Hurst, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc: Neurology, MED	(10) Assoc Investigators:
(11) Key Words: Carnitine	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: New Study b. Review Results: N/A

c. Number of Subjects Enrolled During Reporting Period: 1

d. Total Number of Subjects Enrolled to Date: 1

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective:
Emergency Use: L-Carnitine

(16) Progress: The use of carnitine was discontinued when patient failed to respond to therapy. No side effects were encountered. The drug was returned to the maker.

Publications and Presentations: None

SURGERY

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 73/219 (3) Status: Ongoing

(4) Title:

Treatment of Urinary Tract Trauma in the Laboratory Animal

(5) Start Date: May 1973	(6) Est Compl Date: Indefinite
(7) Principal Investigator: LCDR William E. Shipton, MC	(8) Facility: FAMC
(9) Dept/Svc: Surgery/Urology	(10) Assoc Investigators: Cpt John Wolthuis,MC; Cpt Winston Vaught,MC; Maj Isabelo Castillo,MC LTC Torrence Wilson, MC; LTC Michael J. Raife, MC; LTC Jonathan Vordermark, MC; Col H. E. Favuer, MC
(11) Key Words: Trauma Renal transplantation Inosine	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period: N/A

d. Total Number of Subjects Enrolled to Date: N/A

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective:

Investigation of, and comparison of various modes of treatment of urological trauma with emphasis on newer surgical techniques to include renal vascular repair, bench surgery, autotransplantation and pre- and intraoperative chemical intervention, e.g., use of inosine.

(16) Technical Approach:

Various techniques of vascular reanastomosis and autotransplantation will be performed. Function preservation in the face of these surgeries, and in face of temporary suspension of renal blood flow will be evaluated using inosine as a preservative. IVP and/or renal scans may be used at intervals to ascertain success or failure.

(17)

Progress:

This protocol continues to be an invaluable and irreplaceable tool for teaching of residents and staff.

PRESENTATIONS for FY 84 Annual Progress Report Proto No. 73/219

SERVICE Urology DEPARTMENT Surgery

(1) Levisay, G.L.: Renal Autotransplantation in the Dog. Presented: Kimbrough Urological Seminar, Washington, D. C., January 1974.

(2) Levisay, G.L.: Renal Autotransplantation in the Dog. Presented: South Central Section Meeting of the AUA, Denver, CO, September 1974.

(3) Jackson, J.E.: Renal Autotransplantation with Partial Nephrectomy in the Dog. Presented: South Central Section of the AUA, Denver, CO, 15-19 September 1974.

(4) Jackson, J.E.: Renal Autotransplantation with Partial Nephrectomy in the Dog. Presented: Kimbrough Urological Seminar, San Antonio, TX, 14-19 November 1974.

(5) Page, M.E.: Renal Autotransplantation with Vena Caval Occlusion. Seattle, Washington, October 1975.

(6) Page, M.E. and Weigel, J.W.: Exhibit-renal transplantation with Proximal Vena Caval. Presented: South Central Section Meeting in Urology, September 1975.

PUBLICATIONS:

(1) Levisay, G.L.: Renal Autotransplantation in the Dog. Proc of the Kimbrough Urolo Sem, January 1974.

(2) Jackson, J.E.: Renal Autotransplantation with Partial Nephrectomy in the Dog. Proc of the South Central Sect, AUA, Denver, CO 15-19 September 1974.

(3) Page, M.E.: Renal Autotransplantation with Venal Caval Occlusion. Proc of the Kimbrough Urolo Sem, Seattle, WA, 5 October 1975.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 78/200 (3) Status: Ongoing

(4) Title:

Anastomosis of the Dog Vas Deferens Using Microsurgical Technique

(5) Start Date: April 1978	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Col Howard E. Fauver, M.D., MC	(8) Facility: FAMC
(9) Dept/Svc: Surgery/Urology	(10) Assoc Investigators: Lt Col Torrence M. Wilson, MD Lt Col Michael J. Raife, MD LCDR William E. Shipton, MD Cpt John S. Wolthuis, MC Cpt Winston W. Vaught, MC Maj Isabelo Castillo
(11) Key Words: Microsurgery-vasovasostomy	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: N/A

d. Total Number of Subjects Enrolled to Date: N/A

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A

(15) Study Objective:

To master the microsurgical anastomosis of the vas deferens.

(16) Technical Approach: Standard bilateral vasectomy performed on mongrel male dogs. Three weeks later a two layer microsurgical anastomosis using 10-0 nylon is completed. Three weeks later the dog is sacrificed and bilateral vasograms completed.

(17) Progress: This protocol continues to be an invaluable and irreplacable tool for teaching of residents and staff in the technique of microsurgery.

Continuing experimentation with various sutures and microsurgical technique is being performed. Since it is felt that a minimum of thirty hours of microscope time is essential before this procedure can be performed in human subjects, this current protocol represents the only practical way in which experience can be gained.

Publications: Vaccaro, J.A.: Microscopic Vasovasostomy: The Fitzsimons Experience. Kimbrough Urological Proceedings, Vol. 14, 1980.

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 78/201 (3) Status: Ongoing

(4) Title:

Clinical Study for Intraocular Lens

(5) Start Date: September 1976	(6) Est Compl Date: Unknown
(7) Principal Investigator: Floyd M. Cornell, M.D.	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators: Douglas A. Freeley, M.D., LTC/P, MC John A. McCubbin, M.D., CPT/P, MC William R. Wilson, M.D., MAJ, MC Anthony R. Truxal, M.D., CPT, MC Ricardo J. Ramirez, M.D., CPT, MC
(11) Key Words:	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Apr 83 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 300 implants

d. Total Number of Subjects Enrolled to Date: 1100 intraocular lenses

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

1). To determine postoperative visual acuity of patients receiving an intraocular lens, and to compare those results with those of a control group of patients who undergo cataract surgery but do not receive an intraocular lens.
2). To describe the occurrence and time course of postoperative ocular complications and adverse reactions both for intraocular lens implant subjects and for control subjects.
3). To compare the occurrence of adverse reactions and ocular complications in the implant group and in the control group, in order to delineate any significant difference.
4). To describe the occurrence of postoperative lens complications for the implant group, and their relationship to ocular complications.
5). To identify subgroups within the implant study population that are at "high risk" of particular complications as compared to the control group.

(16) Technical Approach:

After didactic courses, observations, laboratory practice and assistance with an experienced implant surgeon, a surgeon who can perform an accomplished cataract extraction, is then allowed to perform intraocular lens surgery under proper tutorage. Postoperative examinations include: pachyometry, keratometry, and specular microscopy. Contraindications to surgery include: patients with good visual potential in only one eye, proliferative diabetic retinopathy,

(cont'd)

CONTINUATION SHEET, FY 84 ANNUAL PROGRESS REPORT Proto No.: 78/201

(10)
Michael J. Trynosky, M.D., CPT, MC
Luis E. Colon, M.D. CPT/P, MC

(16)
rubeosis irides, high axial myopia, and inadequately controlled glaucoma, Fuch's endothelial dystrophy, and a history of previous retinal detachments or uveitis.

(17) Progress:
Due to the initial 25 implants between September 1976 and February 1978, the implantation of intraocular lenses at FAMC was expanded. We now have implanted over 1100 intraocular lenses.
As a result of the past seven years experience, we have evolved better guidelines for patient selection, better surgical techniques and improved guidance for postoperative care. Our study includes tabulation of operative complications, postoperative complications, visual results, endothelial cell loss, corneal thickness changes, changes in corneal astigmatism, and residual refractive error.

The results of every ophthalmologist implanting intraocular lenses in the United States is additionally compiled by computer in Washington, D.C. by the FDA. Our results are a small part of this overall study. Final data from this massive study is to be completed in the future. As a result of this study many intraocular lenses have been taken off the protocal due to their proven safety. These devices that have been taken off the protocol study need only be registered when implanted at this time. Others have been discontinued from manufacture as a result of the development of superior lens devices.

Publications: None

CONTINUATION SHEET for Annual Progress Report 84 Protocol No 83/203

DEPARTMENT: Surgery SERVICE: Ophthalmology

(17) Progress: continued

Low-dose laser trabeculoplasty seems to be effective in the treatment of open angle glaucoma. Risks remain minimal as no complications have occurred. Benefits are a lowering of the intraocular pressure. The rate of "failure" of the trabeculoplasty seems to reflect the rate of worsening of the glaucoma.

Publications and Presentations: none

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/203 (3) Status: Ongoing

(4) Title: **Laser Trabeculoplasty: Correlation of the Number of Laser Applications to Short- and Long-Term Effects**

(5) Start Date: **April 1983**	(6) Est Compl Date: **1984**
(7) Principal Investigator: **CPT John A. McCubbin, MC** **MAJ William G. Carey, MC**	(8) Facility: **FAMC**
(9) Dept/Svc: **Surgery/Ophthalmology**	(10) Assoc Investigators: **Ronald R. Holweger, MAJ, MC** **Thomas H. Mader, MAJ, MC** **William R. Wilson, CPT, MC**
(11) Key Words: **laser trabeculoplasty** **intraocular pressure** **trabecular meshwork**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Apr 84 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 20

d. Total Number of Subjects Enrolled to Date: 20

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". 0

(15) Study Objective: **This study is designed to correlate the number of laser burns applied during laser trabeculoplasty in patients with simple chronic open angle increase in intraocular pressure.**

(16) Technical Approach: Selected patients will randomly be assigned the number of laser burns to be applied to each eye. Patients will be assigned either 10, 20, 30, or 40 burns in the inferior 180° of each eye. The patients will be followed during the immediate post-procedure period and closely monitored for complications and then followed for a period of one year at least to determine the long-term efficacy.

(17) Progress: A total of 40 eyes in 20 patients have been entered into the study, and Argon laser trabeculoplasties have been performed on these eyes. Three patients have returned to their original intraocular pressures or above, requiring additional medical control of their glaucoma. All patients have had a lowering of intraocular pressure during the initial months following the trabeculoplasty. Three subjects at or around 6 months after a steady pressure rise surpassed safe levels and required additional medication. These patients had the more advanced glaucoma going into the study. This is felt to reflect a worsening of the glaucoma and not secondary to the procedure.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/202 (3) Status: Ongoing

(4) Title: Microbiology of Eyebank Eyes Taken from Septic Donors

(5) Start Date: October 1983	(6) Est Compl Date: Unknown
(7) Principal Investigator: Andrew J. Cottingham, Jr., M.D.	(8) Facility: FAMC
(9) Dept/Svc: Ophthalmology/Surgery	(10) Assoc Investigators: Douglas A. Freeley, LTC, MC; Calvin E. Mein, MAJ, MC; Floyd M. Cornell, MAJ, MC; Ronald R. Holweger, MAJ, MC; John A. McCubbin, CPT, MC (con'd)
(11) Key Words: Eye Bank, Septic, Donor Eyes, Corneal Transplant	
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	(13) Est Accum OMA Cost:*

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: The questions this project shall attempt to answer are:
1) What is the incidence of positive cultures from various compartments of eyes taken from potentially bacteremic or septic donors?
2) What donor factors affect the incidence of positive cultures or species of organism(s) cultured?
3) Does the manner in which the tissues is handled or stored affect the incidence of positive cultures?
4) What is the origin of the bacteria cultured from the cornea and within the eye? Does it correlate with organisms known or suspected to be present systemically?

(16) Technical Approach: Eyes from septic death cases and control non-septic death cases are cultured (one eye immediately and one after storage at 4^{o}C for 48 hours). The culturing techniques are accomplished in multiple ways.

(17) Progress: Suitable donor material for this project has not been as readily available as anticipated. From the onset of the project only two pair of donor eyes have been available.

(10) continued: William R. Wilson, CPT, MC; Anthony R. Truxal, CPT, MC; and Ricardo J. Ramirez, CPT, MC

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/201 (3) Status: Ongoing

(4) Title:

CT Diagnoses of Medial Meniscal Tears

(5) Start Date: 1 May 83	(6) Est Compl Date: 1 May 85
(7) Principal Investigator: CPT Ricky Wilkerson, MC LTC Walton W. Curl, MC CPT Marlene J. Severson, MC	(8) Facility: FAMC
(9) Dept/Svc: Orthopedic/Surgery	(10) Assoc Investigators: none
(11) Key Words: Medial meniscus Tears and CT Scan	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: N/A b. Review Results: N/A

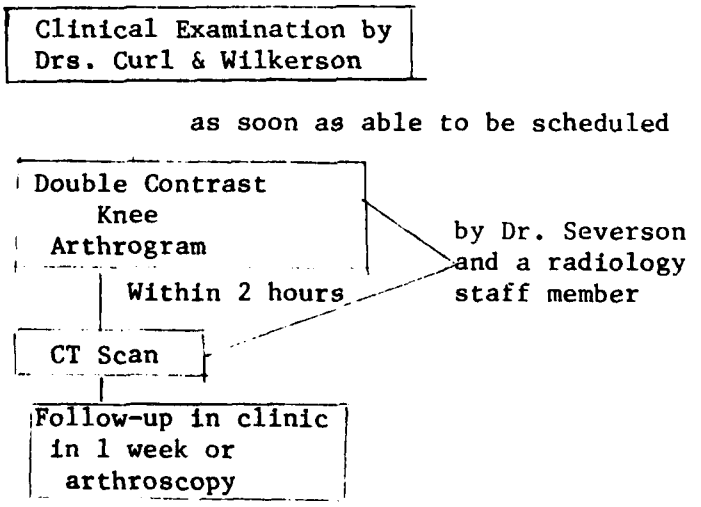
c. Number of Subjects Enrolled During Reporting Period: 5

d. Total Number of Subjects Enrolled to Date: 5

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". none

(15) Study Objective: To evaluate the possible usefulness in diagnosis of medial meniscal tears of the knee using the CT scan and to compare it to the accuracy of the knee arthrogram. Subject population will consist of approximately 15 adult patients who on physical examination have suspected medial meniscal tears.

(16) Technical Approach:



(17) Progress: To date, 5 knees have been examined and arthroscoped. These 5 patients were all identified during fiscal year 83. Currently the results are equivocal, however, since only 5 patients have been done, then no conclusive results have been obtained. We are continuing with this protocol, anticipating at least 10 more patients over the next severaly months to include in the protocol.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/200(3) Status: ongoing

(4) Title:

Evaluation of a Nonabsorbable Anterior Cruciate Ligament Prosthesis

(5) Start Date: May 1983	(6) Est Compl Date: May 1984
(7) Principal Investigator: Walton W. Curl, LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Orthopedic/Surgery	(10) Assoc Investigators: Ricky Wilkerson, CPT, MC
(11) Key Words: Anterior Cruciate Ligament and Prosthesis	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

c. Number of Subjects Enrolled During Reporting Period: 6

d. Total Number of Subjects Enrolled to Date: 18

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". none

(15) Study Objective: To determine efficacy of repairing a ruptured anterior cruciate ligament and stinting this repair with an artificial ligament. To determine the biomechanical and histologic parameters of the ligament/prosthetic complex at 6 months and 1 year. To determine the effect of an intra-articular prosthetic device on the articulating cartilage and surrounding synovial tissues within the knee.

(16) Technical Approach: 12 mongrel dogs initially had their left stifle joint used as a control, arthrotomy and rupture of the anterior cruciate ligament, the right knee underwent rupture of the anterior cruciate ligament and augumentation using the patella tendon with supplementation using an artificail ligament prosthesis. Originally the intent was to sacrifice 6 of the dogs at 6 months and 6 of the dogs at 12 months and then study the synovium and cruciate ligament complex both histologically and histochemically.

(17) Progress: The first 6 dogs are completed, the second 6 to be sacrificed in 1984. The limbs are sent to Howmedica for evaluation, no conclusions can be made yet.

Publications and Presentations: none

CONTINUATION SHEET, FY 84 ANNUAL PROGRESS REPORT Proto No.: 82/205

Publications: None

Presentations: Houseworth, Stephen W., Curl, Walton W., Smith, Cheryl K. and Eilert, Robert E. Use of the Arthroscope to Evaluate Immediate and Delayed Anterior Cruciate Ligament Reconstruction: An Experimental Study in the Dog: Presented: Yearly Barnard Seminar with the University of Colorado Orthopedic Surgery Program, 5 December 1984.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/205 (3) Status: Completed

(4) Title: The Effects of Immediate and Staged Repair of the Torn Anterior Cruciate (cranial cruciate) Ligament in Dogs as Evaluated by Serial Arthroscopic Examinations

(5) Start Date: April 1983	(6) Est Compl Date: May 1984
(7) Principal Investigator: Stephen W. Houseworth, CPT, MC	(8) Facility: FAMC
(9) Dept/Svc: Orthopedic/Surgery	(10) Assoc Investigators: Robert E. Eilert, M.D. Cheryl K. Smith, DVM, CPT
(11) Key Words: Anterior Cruciate Ligament and Arthroscopy	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

c. Number of Subjects Enrolled During Reporting Period: 12

d. Total Number of Subjects Enrolled to Date: 12

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to evaluate arthroscopically the effects of staged anterior cruciate ligament repairs with augumentation in the dog knee(stifle). Specific attention will be directed at the onset and progression of degenerative changes within the joint.

(16) Technical Approach: 12 dogs have been divided into 3 groups of 4 dogs one knee joint of each dog will be used as a control and the other for an operative procedure. 3 of the dogs will have a repair of the anterior cruciate ligament with augumentation, 3 dogs will have repair of the anterior cruciate ligament with augumentation one month following the initial section of the anterior cruciate ligament and group 3 will have augumented repairs of the anterior cruciate ligament 3 months following initial section of the ligament. All dogs will have arthroscopic examination at 6, 8, 12, 16, 32 and 40 weeks, and will be sacrificed.

(17) Progress: The protocol has been completed. A total of 186 arthroscopic procedures were performed. IN May 1984, the dogs were euthanized and a post mortem examination was performed on each knee (stifle). The paper from this project has been completed. It has currently been submitted for a National Sports Medicine Research Award.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/204 (3) Status: Completed

(4) Title: Evaluation of Treatment Methods for Extravasation of Chemotherapeutic Agents

(5) Start Date: August 1982	(6) Est Compl Date: July 1983
(7) Principal Investigator: Timothy Loth, MD CPT, MC	(8) Facility: FAMC
(9) Dept/Svc: Surgery/Orthopedic	(10) Assoc Investigators: William W. Eversmann, Jr., MD COL, MC
(11) Key Words: chemotherapeutic extravasation necrosis	
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	(13) Est Accum OMA Cost:*

(14) a. Date, Latest HUC Review: July 83 b. Review Results: Completed

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To evaluate and compare various methods of treating experimental chemotherapeutic agent extravasations.

(16) Technical Approach: A rat model was used in which a number of vesicants were injected into thin skin and treated using surgical debridement or conventional antidotes. One study on each animal served as a control.

(17) Progress: This study was re-opened to increase numbers of animals for statistical evaluation. The paper has been re-submitted to JHS, and is awaiting their evaluation.

Publications: None.

Presentations:

1. Loth, T.S. and Eversmann, W.W.: Evaluation of Treatment Methods for the Extravasation of Chemotherapeutic Agents: A Comparative Study. Presented: Third Annual Military Current Concepts in Hem/Onc Meeting, San Antonio, TX, 1983.

2. Loth, T.S. and Eversmann, W.W.: Evaluation of Treatment Methods for the Extravasation of Chemotherapeutic Agents: A Comparative Study. Presented: Joseph E. Baugh Resident Competition, Washington, D.C., 1983.

3. Loth, T.S. and Eversmann, W.W.: Evaluation of Treatment Methods for the Extravasation of Chemotherapeutic Agents: A Comparative Study. Presented: American Society for Surgery of the Hand Annual Meeting, Atlanta, GA, February, 1984.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/203-N (3) Status: Ongoing

(4) Title:

Effectiveness of EMG Biofeedback in Maintaining Fluency Obtained in an Intensive Stuttering Treatment Program

(5) Start Date: 1982 (6) Est Compl Date: 30 months after start

(7) Principal Investigator:

Jon M. Hasbrouck, Ph.D.

(8) Facility: FAMC

(9) Dept/Svc: Surgery/Speech Path

(10) Assoc Investigators:

Fran Lowry-Romero, M.S.

(11) Key Words:

Stuttering
Biofeedback

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 18

d. Total Number of Subjects Enrolled to Date: 28

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

NA

(15) Study Objective: Compare effects of extensive EMG biofeedback training and practice to EMG monitoring with no biofeedback and to no EMG monitoring and no biofeedback, to determine how EMG biofeedback related to the acquisition and maintenance of fluency in an intensive adult stuttering treatment program.

(16) Technical Approach: SS in 3 groups will be pretested, receive 3 concurrent treatment procedures (airflow, relaxation, biofeedback) followed by a 4th treatment (discriminative stimulus control) and be post-tested. Grp. 1 will receive extensive EMG biofeedback monitoring, training, and practice. Grp. 2 will receive the same treatment as Grp. 1, but will receive no auditory and visual feedback of performance. Grp. 3 will receive no EMG biofeedback training or monitoring, but will receive the same amount of time in activities similar to Grps. 1 and 2.

(17) Progress: During this fiscal year, 18 subjects in Grps 3 have completed the specified treatment program and have been followed on a regular basis since release from treatment. Group 2 SS will be the next subjects to be run in addition to additional Group 1 SS.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/202 (3) Status: Terminated
(4) Title: Lateral electrical stimulation for the treatment of scoliosis

(5) Start Date: March 1982	(6) Est Compl Date: March 1986
(7) Principal Investigator: Joe K. Ozaki, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Orthopedic/Surgery	(10) Assoc Investigators:
(11) Key Words: Scoliosis	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 5
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None.

(15) Study Objective: To demonstrate the nocturnal transcutaneous electrical stimulation of paraspinal muscles is as effective as the use of a full-time spinal orthosis (brace) in the treatment of idiopathic scoliosis occurring in skeletally immature adolescents.

(16) Technical Approach: The scoliosis patients who qualify for the study will be fit with electrical stimulation unit and instructed in its use. They will then have a two week trial period at home to insure that they can conform to the protocol. They are then followed closely at regular intervals to ascertain the outcome.

(17) Progress: Since the scolitron one unit has been cleared by the FDA for general use as of 6 Jan 83, the protocol will be discontinued.

Publications and Presentations: none

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/201 (3) Status: Ongoing

(4) Title: Prospective Double Blind Randomized Study of the Effects of Supplemental Dietary Calcium and Vitamin D on the Healing of Distal Radius Fractures in Adults

(5) Start Date: January 1982	(6) Est Compl Date: 1986
(7) Principal Investigator: Timothy S. Loth, M.D. Captain, MC	(8) Facility: FAMC
(9) Dept/Svc: Surgery/Orthopedic	(10) Assoc Investigators: Steve Flood, M.D., CPT, MC Peter Blue, M.D., LTC, MC Nasser Ghaed, M.D., COL, MC
(11) Key Words: Dietary Calcium Dietary Vitamin D Fractures	
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	(13) Est Accum OMA Cost:*

(14) a. Date, Latest HUC Review: 4/83 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 9

d. Total Number of Subjects Enrolled to Date: 14

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine whether dietary calcium can increase the rate and quality of fracture healing.

(16) Technical Approach: Volunteers will be assigned randomly to Group A (which will receive calcium and vitamin D) or Group B (which will receive placebo). Bone densities will be performed on both wrists 3,6,12, and 24 who after fracture. An additional bone density will be performed within 1 week of fracture on the uninjured extremity to act as a control. After 50 cases have been collected the code will be broken for this study.

(17) Progress: We have enrolled 14 patients in the study thus far. Additional cases will be required prior to final analysis.

Publications and Presentations: none.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 81/202 (3) Status: Completed

(4) Title: Treatment of Recurrent Otitis Media: Chemoprophylaxis va Tympanostomy Tubes

(5) Start Date: January 1982	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Carlos Gonzales, MD COT, MC	(8) Facility: FAMC
(9) Dept/Svc: Surgery/ENT	(10) Assoc Investigators: James Arnold, MD, CPT, MC John W. Kolmer, MD, COL, MC Thomas Kueser, MD, CPT, MC Edward A. Woody, MD, CPT, MC
(11) Key Words: recurrent otitis media tympanostomy tubes chemoprophylaxis	
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	(13) Est Accum OMA Cost:*

(14) a. Date, Latest HUC Review: Jan 84 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 56

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". none

(15) Study Objective: To determine which modality of treatment for recurrent otitis media, chemoprophylaxis or P.E. tubes or both and if one or both offers better control of future otitis media episodes considering morbidity and complications.

(16) Technical Approach: Patients who meet criteria of study will be randomly placed in three different groups. Patients will be followed on a monthly basis for six months. Episodes of recurrent otitis media will be reported and seen by us.

(17) Progress: This protocol will be continued until 65 patients are enrolled and followed for 6 months. Dr. Arnold, Associate Investigator, has been transferred to MAMC where he is to start this protocol and results will be combined.

Publications and Presentations: none

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 80/201 (3) Status: Terminated

(4) Title: Comparison of Cardiac Output and Left Ventricular Stroke Work Before and After Standard Anesthesia Induction of Patients Undergoing Surgical Correction of Combined Mitral Valve Disease and Coronary Artery Disease

(5) Start Date: Oct 1980	(6) Est Compl Date:
(7) Principal Investigator: William J. Reynolds, MD LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Surgery/Anes&Opr Svc	(10) Assoc Investigators:
(11) Key Words: fantanyl, cardiovascular anesthesia, coronary artery disease, mitral valvular disease, open heart surgery	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Oct 83 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: 5

d. Total Number of Subjects Enrolled to Date: 11

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". none

(15) Study Objective: To determine the presence or absence of significant statistical difference of left ventricular work as affected by conventional cardiac anesthesia techniques.

(16) Technical Approach: Real-time data is obtained from pulmonary artery and radial artery catheters using transistor-generated analog data. Portable digital microprocessor provides all second generation data analysis. Cardiac anesthesia uses routine technique.

(17) Progress: Study was terminated due to the transfer of principal investigator.

Publications and Presentations: none

DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &
HSPA-I Ltr,
8 July 1982

(1) Date: FY 84 (2) Protocol WU Nr.: 80/200 (3) Status: Terminated
(4) Title: Hearing Loss in Hypothyroidism

(5) Start Date: 1980 (6) Est Compl Date:
(7) Principal Investigator (8) Facility: FAMC
Marc Sachs, CPT, MC

(9) Dept/Svc: Surgery/Otolaryngology (10) Assoc Investigators:
(11) Key Words:
hypothyroidism
hearing loss

John Kolmer, COL, MC
Fred Hofeldt, COL, MC

(12) Accumulate MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:
c. Number of subjects enrolled during reporting period:
d. Total number of subjects enrolled to date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.:

(Continue on a separate sheet, designating this continuation as (14)e.)

(15) Study Objective: The objectives are to determine if there is a relationship of hearing loss to hypothyroidism, the locus of this defect, and the potential reversability of this effect.

(16) Technical Approach: Newly diagnosed hypothyroid patients are given a routine hearing evaluation, tympanograms and a BSER. They are then restudied four weeks after beginning therapy, and again at least twelve weeks later.

(17) Progress: Terminated - Principal Investigator failed to reply.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/204 (3) Status: Ongoing

(4) Title: The Role of Minimal Surgical Debridement in the Treatment of Vesicant Extravasations

(5) Start Date: Sept. 83	(6) Est Compl Date: Dec. 84
(7) Principal Investigator: Timothy S. Loth, M.D. Captain, MC	(8) Facility: FAMC
(9) Dept/Svc: Surgery/Orthopedics	(10) Assoc Investigators:
(11) Key Words: Extravasations Vesicants Debridement	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study was to define the role of minimal surgical debridement in the treatment of vesicant extravasations.

(16) Technical Approach: An animal model was employed to determine the efficacy of minimal surgical debridement on vesicant extravasations. Rats were injected bilaterally in the flanks with one side being operated on at various intervals while the opposite side was unoperated on and served as a control. Serial measurements of ulcer diameter up to 35 days after the vesicant injection were compared among the treatment groups and controls to determine the effectiveness of surgery in limiting ulcer size and in decreasing the number of persistent ulcers. Agents tested were doxorubicin, renograph, and fluroscene.

(17) Progress: The first phase of this study has been completed which demonstrated that minimal surgical debridement is an effective means of preventing vesicant induced ulcers and of limiting their size in doxorubicin extravasations. This paper was presented to the Hugh Mahon Lectureship in 1984 and to the Mid-Central States Orthopedic Society. Ongoing work is in progress to define the role of early surgical debridement in renograph and extravasations.

PRESENTATIONS FOR FY 84 Annual Progress Report **Proto No.** 83/204

SERVICE Orthopedics **DEPARTMENT** Surgery

Denver Children's Hospital Orthopaedic Day, April 26, 1984
Mid-Central States Orthopedic Society Resident's Award, June 1, 1984
Hugh Mahon Lectureship Award, Denver, Colorado, June 1984

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/200 (3) Status: Terminated

(4) Title: Prevention of Macular Injury From High Illumination Levels of the Operating Room Microscope by the Use of a Corneal Light Blocking Device

(5) Start Date: Feb 84	(6) Est Compl Date:
(7) Principal Investigator: Ronald R. Holweger, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc: Opth/Surgery	(10) Assoc Investigators:
(11) Key Words: opaque filter	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The primary objective in this investigation is to do a randomized study using an opaque filter to block the high illumination from falling on the cacula and to then demonstrate with certain objective criteria the effectiveness or non-effectiveness of ligh blocking procedures.

(16) Progress:

The study was terminated due to the transfer of the Principal Investigator.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/201 (3) Status: Ongoing

(4) Title: Q-Switched Nd: YAG Laser in Discission of Secondary Membranes (Device: Microruptor MR-2 Nd: YAG Laser; MFR: LASAG AG, Thun, Switzerland; Sponsor: VTI, Inc., Torrance, CA)

(5) Start Date: Feb 84	(6) Est Compl Date:
(7) Principal Investigator: Douglas A. Freeley, LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Opth/Surgery	(10) Assoc Investigators:
(11) Key Words: YAG Laser	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 55

d. Total Number of Subjects Enrolled to Date: 55

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The overall purpose of this study is to determine the degree of safety and efficacy of the MR-2 Nd:YAG laser manufactured by LASAG AG of Thun, Switzerland, in performing non-invasive intraocular surgery for discission of secondary membranes.

(16) Technical Approach: Subjects will be chosen out of a candidate propulation of patients who are visually symptomatic from opacified secondary membranes but with healthy eyes. These candidates will be reviewed for contraindications to laser therapy. They will be in a state of health which will allow them to be able to sit at the laser surgical unit without discomfort. Patients entering the study will be given a preoperative evaluation including slit lamp microscopy and ophthalmoscopy.

(17) Progress: To date 55 patients have been entered in the study. There have been no problems encountered thus far - will continue to enter patients in the study.

Publications and Presentations: None

CLINICAL INVESTIGATION

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 72/302 (3) Status: Ongoing

(4) Title: **Comparison of Metabolic and Functional Changes in Defects of Platelet Function**

(5) Start Date: **1972**	(6) Est Compl Date: **1984**
(7) Principal Investigator: **Donald G. Corby, M.D.,COL,MC,**	(8) Facility: FAMC
(9) Dept/Svc: **DCI/Biochemistry Svc**	(10) Assoc Investigators: **T.P. O'Barr, Ph.D., DAC**
(11) Key Words: **platelet function newborn**	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 11/82 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: **To correlate biochemical and functional parameters to gain a better understanding of the pathophysiology of the disorders of platelet function.**

(16) Technical Approach:

Subjects: In most part, this study will deal with the further investigation of the platelet "defect" found in the normal newborn infant. However, since the techniques of studying the biochemical aspects of platelet function developed in previous studies permit the thorough evaluation of qualitative platelet disorders in older children and adults, the protocol is also intended to cover the diagnostic evaluation of patients with functional platelet syndromes associated with the "hemorrhagic state".

Platelet Function Studies: When indicated clinically, platelet counts, bleeding times, platelet adhesion, and whole blood and PRP aggregation in response to ADP, collagen, epinephrine, or ristocetin will be performed in the Coagulation Section, Department of Pathology or the Biochemistry Service, Department of Clinical Investigation.

(16) Technical Approach (cont'd):

Biochemical Studies: Assessment of the content and release of the content of the platelet's subcellular storage organelles (alpha and dense granules) and evaluation of the Platelet membrane will include, but not be limited to the following:

a. Electron microscopy and mepacrine staining of dense granules.
b. Content of platelet factor 4 and B-thromboglobulin activity in the alpha granules.
c. Production of platelet-derived growth factor by ^{3}H-thyamide incorporation in 3T3 mouse fibroblasts by platelet lysates.
d. Measurement of secretable acid hydrolases (B-glucuronidase, B-galactosidase, and membrane P-nitrophenyl phosphatase) activities.
e. Membrane glycoprotein and phospholipid content.
f. Release of arachidonate from membrane phospholipids by phospholipase C and diglyceride lipase.
g. Mobilization of Ca++.
h. Other studies as they become available.

(17) Progress: Due to the need to assign personnel for other approved protocols and shortage of personnel due to transfers and resignations, work on this protocol has been temporarily discontinued. We intend to evaluate leucotrienes plus lipooxygenase pathway products derived prostaglandins, and begin work on phosphorylative schema in newborn platelets in the next FY.

PUBLICATIONS for FY 84 Annual Progress Report Proto No. 72/302

DEPARTMENT of Clinical Investigation

(1) Corby, D.G., Shigeta, F.H., Greene, H.L., and Stifel, F.B.: Platelet Dysfunction in Glycogen Storage Disease Type I (GSDI): Reversal with Total Parenteral Alimentation (TPA). (Abst.) Clin. Res. 21:304, 1973.

(2) Corby, D.G., Preston, K.A., Shigeta, F.H., O'Barr, T.P., and Zuck, T.F.: Adverse Effect of Gel Filtration on the Adenine Nucleotides of Human Platelets. (Abst., P. 107), III Congress, International Society on Thrombosis Hemostasis (Vienna, Austria), June 1973.

(3) Corby, D.G., (Intr. by Wm. E. Hathaway): Mechanism of Platelet Dysfunction in Newborn Infants. J. Ped. Res., Vol. 8, No. 4, April 1974.

(4) Corby, D.G., Preston, K.A., O'Barr, T.P.: Adverse Effect of Gel Filtration on the Function of Human Platelets. Proceedings of the Society for Experimental Biology and Medicine, 146:96-98, 1974.

(5) Corby, D.G., Putnam, C.W., Greene, H.L.: Impaired Platelet Function in Glucose-6-Phosphatase Deficiency. The J. Ped., 85:71-76, July 1974.

(6) Corby, D.G., and Zuck, T.F.: Newborn Platelet Dysfunction: A Storage Pool and Release Defect. Thrombosis and Haemostasis, 36:200-207, 1976.

(7) Corby, D.G., Goad, W.C., Barber, J., and O'Barr, T.P.: Evaluation of Cyclo-Oxygenase Pathway in Platelets of the Newborn, Thrombosis and Haemostasis (Stuttgart), 38:35, 1977 (Abstract).

(8) Corby, D.G., O'Barr, T.P.: Decrease in -Adrenergic Binding Sites in Newborn Platelets: Cause of Abnormal Response to Epinephrine? Blood, 52:161, 1978.

(9) Corby, D.G.: Aspirin in Pregnancy: Maternal and Fetal Effects. Pediatrics, 62:930, 1978.

(10) Corby, D.G., O'Barr, T.P.: Decreased Alpha-Adrenergic Receptors in Newborn Platelets: Cause of Abnormal Response to Epinephrine. Dev Pharmacol & Ther, 2:215-225, 1981.

(11) Corby, D.G., O'Barr, T.P.: Neonatal Platelet Function: A Membrane-Related Phenomenon. Haemostasis, 10(4):177-232, 1981.

Publications for FY 84 Annual Progress Report (72/302) - continued

(12) Corby, D.G., O'Barr, T.P.: Newborn Platelet Function. Chapter in Book "Acquired Bleeding Disorders in Childhood". Masson Publ, pages 31-37, 1981.

(13) Corby, D.G., O'Barr, T.P., and Swanson, E.E.: Evidence for a Deficiency of Alpha-Granule Proteins in the Platelets of Newborn Infants. Soc Ped Res, May 1983.

Presentations:

(1) Corby, D.G., Shigeta, F.H., Greene, H.L., and Stifel, F.B.: Platelet Dysfunction in Glycogen Storage Disease Type I (GSDI): Reversal with Total Parenteral Alimentation (TPA). Presented: Western Society for Pediatric Research, Carmel, California, February 1973.

(2) Corby, D.G., Preston, K.A., Shigeta, F.H., O'Barr, T.P., and Zuck, T.F.: Adverse Effect of Gel Filtration on the Adenine Nucleotides of Human Platelets. Presented: III Congress, International Society on Thrombosis and Hemostasis, Vienna, Austria, June 1973.

(3) Corby, D.G.: Mechanism of Platelet Dysfunction in Newborn Infants, Society for Pediatric Research, APS-SPR, Washington, D.C., May 1974.

(4) Corby, D.G., Goad, W.C., Barber, J., and O'Barr, T.P.: Evaluation of Cyclo-Oxygenase Pathway in Platelets of the Newborn. Presented: VIth International Congress on Thrombosis and Haemostasis, Philadelphia, Pennsylvania, June 1977.

(5) Corby, D.G. and O'Barr, T.P.: Decreased - Adrenergic Receptors in Newborn Platelets: Cause of Abnormal Response to Epinephrine? Presented: VIIth Congress International Society of Thrombosis and Haemostasis, London, England, 1979.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 77/300 (3) Status: Ongoing

(4) Title: **Immunologic Disorders in Children and Adults: 1. Correlation of Immune Functions in the Immunodeficiency State. II. Correlation of Immune Functions of Leukemia and other Childhood Malignancies.**

(5) Start Date: 1 Oct 77	(6) Est Compl Date: Open ended
(7) Principal Investigator: **R. Stephen Whiteaker, Ph.D.** **CPT, MSC**	(8) Facility: FAMC
(9) Dept/Svc: **DCI/Immunology Svc**	(10) Assoc Investigators: **Donald G. Corby, M.D.** **COL, MC**
(11) Key Words: **immunologic disorders**	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Apr 84 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 141
d. Total Number of Subjects Enrolled to Date: 718
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: **Existing specialized immuno-chemical procedures will be consolidated into a registered protocol for use, on a consultative basis, by the hospital staff.**

(16) Technical Approach: A clinical laboratory immunology consultation service has been established. Main emphasis is performance and evaluation of specialized immuno-chemical tests, for training house-staff personnel and consultative support of hospital. The major areas of studies include humoral and cellular immunity and leukocyte function evaluation. Patients are selected on the basis of severity of recurrent infections, clinical immunodeficiency state, lack of response to medical management and availability of Department of Clinical Investigation for laboratory evaluations for patient care.

(17) Progress: A total of 141 patients were evaluated on a consultative basis for immunologic disorders. During this period seven physician house-staff personnel were also trained in laboratory clinical immunology procedures. Patients Studied: 37 in the area of serum protein gammapathies, 43 in the area of cell-mediated function, and 61 in the area of combined humoral-cellular function. Subjects with indicated major findings were as follows: 1) Humoral immunologic disorders -serum protein profile evaluations: 5 cryoglobulinemias, 18 serum protein gammopathies, 7 immunoglobulin disorders (heavy or light chain or benign spike), 5 hypogammaglobulinemias, (cont'd)

CONTINUATION SHEET for FY 84 ANNUAL PROGRESS REPORT Proto. No.: 77/300

(17) Progress: cont'd

12 hypergammaglobulinemias, 3 complement abnormalities; II) Cellular immunologic disorders - 104 lymphocyte transformations, of these 9,5, and 2 patients were recorded suppressed to PHA, PWM, and candida stimulations respectively, 57 T-lymphocyte enumerations with 4 patients recorded as low T-lymphocyte percentages, 57 B-lymphocyte enumerations with 0 patients recorded as abnormal, 32 NBT evaluations with 4 patients recorded as abnormal.

Publications: none

Presentations:

1. Brown, G.L. and Heggers, J.: Medical Mycology: Assessment of Bacteriologic and Seroligic Parameters of Clinically-important Mycoses Normal and Immunologic Comprised Host. Presented: American Medical Technologist Educational Seminars, Denver, CO, July 1979.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 79/300 (3) Status: Terminated

(4) Title: A Study of the Hormone-dependent Growth of Human mammary Tumors In Vitro

(5) Start Date: 1979	(6) Est Compl Date:
(7) Principal Investigator: Charles F. Ferris, Ph.D., CPT, MSC	(8) Facility: FAMC
(9) Dept/Svc:DCI/Cell Physiology	(10) Assoc Investigators: John W. Harbell, Ph.D., CPT, MSC Donald B. Mercill, B.S., DAC SP5 Norman R. Jones, B.S. SP5 Leslie C. Kramer, B.S.
(11) Key Words: breast tumors organ culture	
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	(13) Est Accum OMA Cost:*

(14) a. Date, Latest HUC Review: Mar 83 b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: To examine the hormone requirements for the growth of human mammary tumors using explant organ culture.

(16) Technical Approach: Tissue samples are obtained from biopsy or mastectomy specimens. Each sample is cut into many small pieces and distributed, for culture, in a battery of hormone combinations. Replicate samples from each hormone combination are subjected to the appropriate radiolabelled precursor to determine DNA, RNA, and protein synthesis. Histology and macromolecular synthesis measure response.

(17) Progress: Reasons for termination - 1) meaningful data already compiled and reported, 2) transfer of former principal investigator, and 3) work of Service concentrated on physician protocols more recently approved.

Publications:

1. Harbell, J.W.: Insulin Action on Normal and Transformed GR/A Strain Mouse Mammary Tissues. In Vitro 16(3):247, 1980.

Presentations:

1. Harbell, J.W.: Insulin Action on Normal and transformed GR/A Mouse Mammary Tissues. Presented: 31st Annual Meeting, Tissue Culture Association, St. Louis, MO, June 4, 1980.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 79/301 (3) Status: Completed

(4) Title:
Basic Studies to Hasten Recovery from or Help Prevent Bone Injury

(5) Start Date: 1979

(6) Est Compl Date: October 1984

(7) Principal Investigator:
David T. Zolock, MAJ, MSC

(8) Facility: FAMC

(9) Dept/Svc: DCI/Biochemistry Svc

(10) Assoc Investigators:
David D. Bikle, MD, PhD, Veterans Administration Med. Ctr. San Francisco, CA
Elwyn Chadwick, SP6

(11) Key Words:
vitamin D, calcium, bone, intestine, calcium binding protein

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: To reduce the incidence of fracture wounds and to reduce the time involved to heal fracture wounds by increasing the absorption and retention of calcium and phosphorus through nutritional and medical therapeutic improvements.

(16) Technical Approach: Since bone mineralization is indirectly regulated by intestinal absorption, the bone as well as the intestinal responses to various therapeutic measure, will be studied. In general, the animal of choice will be chicks which will be fed a vitamin D deficinet diet containing 0.43% phosphorus for approximately three weeks.

(17) Progress: All experiments have been completed and all the data collected. The protocol has been completed and the principal investigator has been transferred to the 10th Medical Laboratory in Germany. A final abstract will be forthcoming.

(17) Progress: cont'd

intestinal mucosa in response to 1,24,25-THCC and 1,25,26-THCC was less than 25% of the response with 1,25-DHCC. When these chicks were given cycloheximide, a protein synthesis inhibitor along with the different metabolites, the intestinal calcium transport was unaffected, but the bone calcium uptake was blocked. Since the stimulated intestinal calcium transport by the vitamin D metabolites does not require protein synthesis, the mechanism of action of the metabolites on the epithelial cell probably is a direct one. A possible mechanism would be the alteration of the membrane structure in the brush border directly by the vitamin D metabolite. Bone calcium uptake does depend on protein synthesis for all three of the vitamin D metabolites. When all the results are compared, 1,25-DHCC is the most active metabolite of the three tested in both the intestine and the bone. Although the results are not significant in all cases, 1,24,25-THCC appeared to be more active in the intestine than 1,25,26-THCC and 1,25,26-THCC appeared to be more active in the bone than 1,24,25-THCC. These results indicate a mechanism of action similar for all three vitamin D metabolites, a mechanism of action which is different for the intestine and the bone, and two different receptor mechanisms with different metabolite specificities for intestinal calcium transport and for CaBP synthesis.

In order to determine if 1,25-DHCC has an effect on the distribution and excretion of calcium in the body, a dose of ^{45}Ca was administered i.v. to rachitic chicks and rachitic chicks receiving a dose of 1,25-DHCC 24 hours before. Serum calcium for the rachitic and 1,25-DHCC treated chicks were 6 and 8 mg/dL, respectively. No significant difference was found between the two groups of chicken in serum ^{45}Ca or bone ^{45}Ca uptake. However, the 1,25-DHCC treated chicks had lower intestinal mucosal accumulation of ^{45}Ca and higher ^{45}Ca content in luminal fluid as compared to the rachitic chicks. These results suggest that 1,25-DHCC not only has an effect on the brush border membrane, but also on the basolateral membrane of the epithelial cell. These results also support our theory that CaBP is necessary for maintaining a low cellular concentration of calcium in the intestinal cell.

PUBLICATIONS:

1. Zolock, David T., Morrissey, Robert L., and Bikle, Daniel D.: Meaning of Non-parallel $1,25(OH)_2D_3$ Mediated Response Relationships in Intestine and Bone to Dose and Time in Vitamin D; Biochemical, Chemical and Clinical Aspects Related to Calcium Metabolism. Walter DeGruter, Inc., New York, 1979.

2. Bikle, Daniel D., Morrissey, Robert L., Zolock, David T. and Herman, R.H.: Stimulation of Chick Gut Alkaline Phosphatase Activity by Actinomycin D and 1,25-dihyroxyvitamin D_3: Evidence for Independent Mechanisms. J Lab Clin Med 94:88-94, 1979.

AD-A154 658 CLINICAL INVESTIGATION PROGRAM ANNUAL PROGRESS REPORT 3/3
(U) FITZSIMONS ARMY MEDICAL CENTER AURORA CO 30 SEP 84

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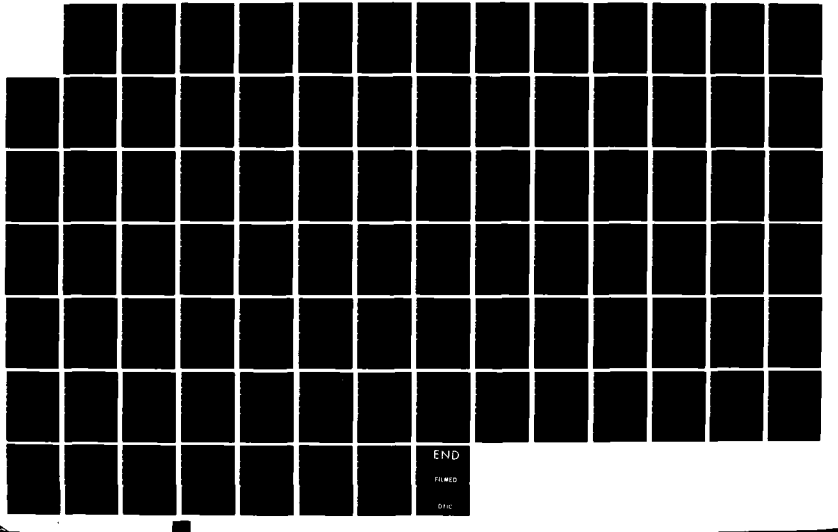

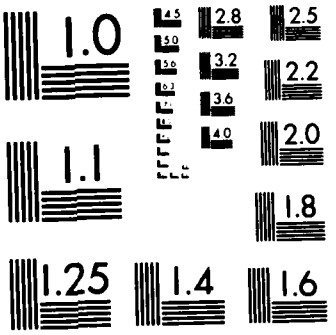

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3. Bikle, Daniel D., Morrissey, Robert L., and Zolock, David T.: The Mechanism of Action of Vitamin D in the Intestine. Am J Clin Nutr 23:2322-2338, 1979.

4. Morrissey, Robert L., Zolock, David T., Mellick, P.W. and Bikle, Daniel D.: Influence of Cycloheximide and 1,24-dihydroxyvitamin D_3 on Mitochondrial and Vesicle Mineralization in the Intestine. Cell Calcium 1:69-79, 1980.

5. Bikle, Daniel D., Askew, E.W., Zolock, David T., Morrissey, Robert L. and Herman R.H.: Calcium Accumulation by Chick Intestinal Mitochondria: Regulation by Vitamin D_3 and 1,25-dihydroxyvitamin D_3. Biochem Pharmacol 89"63-142, 1981.

6. Bikle, Daniel D., Empson, R.N., Morrissey, Robert L., Zolock, David T., Bucci, T.J., Herman, R.H. and Pechet, M.M.: Effect of 1 alpha-hydroxyvitamin D_3 on the Rachitic Chick Intestines: A Comparison to the Effects of 1,12-dihyroxyvitamin D_3. Cal Tiss Int 32:9-17, 1980.

7. Bikle, Daniel D., Morrissey, Robert L., Zolock, David T. and Rasmussen, H.: The Intestinal Response to Vitamin D. Rev Physiol Biochem Pharmacol 89:63-142, 1981.

8. Bikle, Daniel D., Zolock, David T. and Morrissey, Robert L.: Action of Vitamin D on Intestinal Calcium Transport. Annals NY Academy of Sciences 372:481-501, 1981.

9. Charles, M.A., Tirunagura, P., Zolock, David T. and Morrissey, Robert L.: Duodenal Calcium Transport and Calcium Binding Protein Levels in Experimental Diabetes Mellitus. Mineral Electrolyte Metab 5:15-22,1981.

10. Bikle, Daniel D., Peck, C.C., Holford, N.H.S., Zolock, David T. and Morrissey, Robert L.: Pharmacokinetics and Pharmacodynamics of 1,25-dihyroxyvitamin D_3 in the Chick. Endocrin 111:939-946, 1982.

PRESENTATIONS:

1. Zolock, David T., Morrissey, Robert L. and Bikle, Daniel D.: Meaning of Non-parallel 1,25$(OH)_2$ D_3 Mediated Response Relationships in Intestine and Bone to Dose and Time. Presented: Proceedings of the Fourth Workshop on Vitamin D, Berlin (West) Germany, February 1979.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 80/302 (3) Status: Completed

(4) Title: Rapid detection of bacterial antigens in patient specimens using counterimmunoelectrophoresis (CIE)

(5) Start Date: 1 Jan 1981	(6) Est Compl Date: 1 Jun 1984
(7) Principal Investigator: Pari L. Morse, DAC	(8) Facility: FAMC
(9) Dept/Svc: Micro Svc, DCI	(10) Assoc Investigators: Donald D. Paine, DAC Paul G. Engelkirk, LTC, MSC
(11) Key Words: Bacterial antigens Counterimmunoelectrophoresis CIE	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To develop and/or evaluate CIE procedures capable of detecting bacterial antigens in patient specimens within a few hours of receipt.

(16) Technical Approach: Using commercial antisera and published methodologies, we introduced to FAMC the capability of detecting bacterial antigens in patient specimens using CIE. Once reliable procedures were established, Dept of Pathology personnel were trained to routinely perform these procedures.

(17) Progress: a) Bacterial antigen detection: a total of 303 specimens from 257 patients were tested by CIE. Fifty-three (17.5%) of the specimens gave positive results. On 1 Nov 1982, the Microbiology Svc, Dept of Pathology, assumed responsibility for these procedures.

b) Clostridium difficile toxin detection: a total of 263 specimens from 210 patients were tested by CIE. Positive results were obtained on 118 (44.9%) of the specimens. On 1 Jun 1984, the Microbiology Svc, Dept of Pathology, assumed responsibility for this procedure.

PUBLICATIONS for FY 84 Annual Progress Report Proto No. 80/302

SERVICE Microbiology Service DEPARTMENT DCI

Morse, P.L., and Opal, S.M.: (Letter) Adsorption of Clostridium difficile Antiserum for Rapid Detection of Toxin. Diagn. Microbiol. Infect. Dis. 2: 169, 1984.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 80/303 (3) Status: Ongoing

(4) Title: Study of Sensitivity of Tumors to Chemotherapy

(5) Start Date: December 1980	(6) Est Compl Date: indefinite
(7) Principal Investigator: Charles F. Ferris, Ph.D.,CPT,MSC Arlene J. Zaloznik, M.D.,MAJ,MC Elder Granger, MD, CPT, MC	(8) Facility: FAMC
(9) Dept/Svc: DCI/Cell Physiology	(10) Assoc Investigators: John W. Harbell, Ph.D., CPT, MSC SP5 Norman R. JOnes SP5 Leslie Kramer Donald B. Mercill, DAC
(11) Key Words: chemotherapy in vitro, in vivo tumor cell	
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	(13) Est Accum OMA Cost:*

(14) a. Date, Latest HUC Review: Jan 83 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: a) To perform in vitro chemotherapeutic sensitivity testing using tumor cell systems. b) To correlate in vitro chemotherapeutic sensitivity testing results with in vivo chemotherapeutic responses. c) To provide better patient care, i.e., better tumor cell kill, by using in vitro chemotherapeutic sensitivity testing. d) To study alternative therapeutic regimes for various types of solid tumors using the cell lines produced in part a.

(16) Technical Approach: Human tumor cell lines are established in monolayer culture. After purification and cell type varification, replicate cultures are subjected to physiological concentrations of chemotherapeutic agents. Efficacy is determined through measurement of macromolecular synthesis labeling index and cell loss. Correlations between in vitro parameters and patient responses are then established.

(17) Progress: To date, 900 primary cultures from over 196 samples have been processed. Retrospective comparison of in vivo and in vitro responses have been encouraging though firm statistical correlation will require more samples from tumors which respond to chemotherapy. Over 60 cell lines have been produced. Adjunct subprojects using the cell lines and assay system have been completed and presented at national meetings. This also includes basic knowledge used for dermatology service tissue culture protocols.

PUBLICATIONS for FY 84 Annual Progress Report Proto No. 80/303

SERVICE: Cell Physiology DEPARTMENT of Clinical Investigation

1. Moore, G.E., Harbell, J.W., Woods, L.K., Morgan, R.T., and Semple, T.U.: RPMI 8226, a Human Myeloma Cell Line: an Update. (Abst) Proceedings of the American Association for Cancer Research 23:33, 1982.

2. Harbell, J.W. and DiBella, N.J.: Studies on the Interaction of Tetrahydrocannabinol (THC) with Chemotherapeutic Agents Against Human Tumors In Vitro. (Abst) Proceedings of the American Association for Cancer Research 23:226, 1982.

3. Harbell, J.W., Mercill, D.B., Jones, N.R. and Woods, L.K.: Establishment of a Human Leiomyosarcoma Cell Line. (Abst) In Vitro 18(3):295, 1982.

4. Harbell, J.W., Papkoff, J.S. and Daniel, C.W.: Hormone Requirements of the Pregnancy-Dependent Mammary Tumor of GR/A Mice: An In Vitro Study. J Natl Cancer Inst 69(6):1391-1402, December 1982.

5. Harbell, J.W., DiBella, N.J., Jones, L.E., Kramer, L.C., and Mercill, D.B.: Assessment of Synergism Between Hyperthermia (HT) and Chemotherapy (CT) Against Human Melanoma Cell Lines In Vitro. Pro Amer Assoc for Can Res 24:310, 1983 (Abst).

6. Harbell, J.W., Mercill, D.B. and Woods, L.K.: Use of Athymic Nude Mice to Establish Human Tumor Cell Lines. In Vitro 19(3):275, March 1983.

7. Correll, L.L., Neilsen, L.N., Kelleher, P.J., Harbell, J.W. and Minden, P.: Enhanced Immunogenicity of Line-10 Guinea Pig Hepatocarcinoma Cells after Culture. Accepted for Publication in J Natl Cancer Inst, 1983.

8. Wang, V., Gutman, D., Harbell, J., and Moore, G.E.: A Unique Gastrointestinal Cell Line. In Vitro 20(3):246, 1984. (abs)

9. Wang, V., Gutman, D., Harbell, J., and Moore, G.E.: A Cell Line Established from Malignant Distal Renal Tubule Cells. In Vitro (20(3):247, 1984. (Abs)

10. Mercill, D.B., Jones, N.R., and Harbell, J.W.: Human Tumor Cell Destruction by Distilled Water: An In Vitro Evaluation. Cancer (in press).

PRESENTATIONS for FY 84 Annual Progress Report Proto No. 80/303

SERVICE: Cell Physiology DEPARTMENT: of Clinical Investigation

1. Mercill, D.B., Jones, N.R., and Harbell, J.W.: Distilled Water Lavage to Kill Human Tumor Cells: an In Vitro Evaluation of a Traditional Surgical Technique. Presented: Society of Armed Forces Medical Laboratory Scientists Tri-services Annual Meeting, Reno, Nevada, March 1982.

2. Harbell, J.W. and DiBella, N.J.: Studies of the Interaction of Tetrahydrocannabinol (THC) with Chemotherapeutic Agents Against Human Tumors In Vitro. Presented: American Association for Cancer Research, St. Louis, MO, May 1982.

3. Moore, G.E., Harbell, J.W., Woods, L.K., Morgan, R.T., and Semple, T.U.: RPMI 8226, a Human Myeloma Cell Line: an Update. Presented: American Association for Cancer Research, St. Louis, MO, April 1982.

4. Harbell, J.W., Mercill, D.B., Jones, N.R., and Woods, L.K.: Establishment of a Human Leiomyosarcoma Cell Line. Presented: Tissue Culture Association, San Diego, CA, June 1982.

5. Harbell, J.W., DiBella, N.J., Jones, L.E., Kramer, L.C., and Mercill, D.B.: Assessment of Synergism Between Hyperthermia (HT) and Chemotherapy (CT) Against Human Melanoma Cell Lines In Vitro. Presented: American Association for Cancer Research, San Diego, CA, May 1983.

6. DiBella, N.J. and Harbell, J.W.: Interaction of Chemotherapy (CT) and Hyperthermia (HT). Presented: Triservices Medical Oncology Meeting, San Antonio, TX, 1983.

7. Harbell, J.W., Mercill, D.B., and Woods, L.K.: Use of Athymic Nude Mice to Establish Human Tumor Cell Lines. Presented: Tissue Culture Association Annual Meeting, Orlando, FL, June 1983.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 81/302 (3) Status: Completed

(4) Title: Induction of Cerebellar Hypoplasia in Pups by Intrauterine Innoculation of Canine Parvovirus

(5) Start Date: Sep 1982	(6) Est Compl Date:
(7) Principal Investigator: Albert H. McCullen, D.V.M. Captain, VC	(8) Facility: FAMC
(9) Dept/Svc: DCI/Animal Res Svc	(10) Assoc Investigators: Sp5 Leslie C. Kramer Charles F. Ferris, Ph.D., CPT, MSC
(11) Key Words: canine parvovirus cerebellar hypoplasia	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: To determine if canine parvovirus will induce cerebellar hypoplasia in puppies as the feline parvovirus does in kittens.

(16) Technical Approach: Puppies will be taken from the bitches at birth to prevent ingestion of colostrum and fed a commercially available puppy formula. The pups will be divided into four groups. One group of pups will be injected with 0.5ml of virus preparation intraperitoneally and one group will be injected intracerebrally. Control pups will be innoculated with 0.5ml of saline either IP or IC. Pups will then be euthanized at three weeks of age with an overdose of halothane anesthesia. Tissue will be taken for histolopathologic examination to a veterinary pathologist.

(17) Progress: Experimental procedures have been completed on the project. We are currently in the process of writing the paperon the project .

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 81/304 (3) Status: Ongoing

(4) Title: Ultrastructural and immunological aspects of *in vitro* interactions between *Giardia lamblia* trophozoites and host leukocytes.

(5) Start Date: Feb 82	(6) Est Compl Date: Feb 85
(7) Principal Investigator: Paul G. Engelkirk, LTC, MSC Steven K. Koester, DAC	(8) Facility: FAMC
(9) Dept/Svc: Micro & Immunol SvcDCI	(10) Assoc Investigators: Donald D. Paine, DAC Dick J. Wuerz, DAC Stanley L. Erlandsen, Ph.D. Samuel Roger Wetherill, III, MAJ, MSC
(11) Key Words:	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: a) To determine the effects of anti-*Giardia* antibodies, complement and sensitized host cells on the phagocytosis and destruction of *Giardia lamblia* trophozoites *in vitro*. b) To determine the time frame in which host phagocytic cells attach to and phagocytose live *Giardia* trophozoites *in vitro*. c) To determine the host cell types that play a role in the phagocytosis of *Giardia* trophozoites *in vitro*.

(16) Technical Approach: *Giardia lamblia* trophozoites will be incubated with various combinations of host cells, anti-*Giardia* antibodies, and complement. Light microscopic, TEM, and SEM observations will be made to determine the type and extent of host cell/parasite interactions under the various experimental conditions. In addition, Indium-labeled trophozoites will be used in cytotoxicity studies involving human peripheral blood leukocytes.

(17) Progress: Fourteen experiments were conducted during FY 1984: nine Indium experiments, four phagocytosis experiments using human peripheral blood leukocytes, and one complement experiment. a) Cytotoxicity experiments: demonstrated that *G. lamblia* and *Trichomonas vaginalis* trophozoites could be labeled using ^{111}Indium oxine. Human peripheral blood leukocytes are considerably more cytotoxic to *G. lamblia* trophozoites in the presence of heat-labile human serum components (complement?). b) Phagocytosis experiments: demonstrated that human peripheral blood eosinophils are capable of phagocytizing *G. lamblia* trophozoites *in vitro*. Special staining procedures were used to demonstrate the deposition of eosinophil peroxidase onto the surface of partially and fully ingested parasites. A transmission electron micrograph from these studies has been accepted for publication on the cover of the *ASM News* (American Society for Microbiology). c) Complement experiment: The results of this complement experiment indicate that *G. lamblia* trophozoites are capable of activating rat complement, but further experimentation will be necessary to determine whether such activation is by the classical or alternate pathway.

PRESENTATIONS FOR FY 84 Annual Progress Report Proto No. 81/304

SERVICE Microbiology Service DEPARTMENT DCI

Koester, S.K., Engelkirk, P.G., Paine, D.D., Wuerz, D.J., and Rothlauf, M.V.: Influence of Anti-Giardia Antibody, Heat-Labile Serum Components, and Sensitized Host Cells on Short-Term in Vitro Interactions Between G. lamblia Trophozoites and Rat Peritoneal Leukocytes. Presented: Annual Meeting of the American Society for Microbiology, St. Louis, Missouri, March 1984.

Koester, S.K., and Engelkirk, P.G.: Glass Cover Slip Technique for Studying in Vitro Interactions Between Giardia Trophozoites and Host Leukocytes by TEM, SEM, and Light Microscopy. Presented: Rocky Mountain Branch of the American Society for Microbiology, Summer Symposium on Host-Microbe Interactions, Pingree Park, Colorado, August 1984.

Engelkirk, P.G.: Of Eosinophils, Mast Cells, and Parasites. Presented: Rocky Mountain Branch of the American Society for Microbiology, Summer Symposium on Host-Microbe Interactions, Pingree Park, Colorado, August 1984.

PUBLICATIONS:

Koester, S.K., and Engelkirk, P.G.: A Glass Cover Slip Technique for Studying in Vitro Interactions Between Giardia Trophozoites and Host Leukocytes by TEM, SEM and Ligh Microscopy. J. Parasitol. 70: (in press).

Koester, S.K., Engelkirk, P.G., Paine, D.D., Wuerz, D.J., Rothlauf, M.V. and Erlandsen, S.L.: Immunological and Ultrastructural Aspects of Short Term in Vitro Interactions Between Giardia lamblia Trophozoites and Rat Peritoneal Leukocytes. J. Parasitol. (submitted).

DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &
HSPA-I Ltr,
8 July 82

(1) Date: FY 1984 (2) Protocol WU Nr.: 81/305 (3) Status: TERMINATED

(4) Title:
Development of a standardized method for minimal inhibitory concentration (MIC) antibiotic susceptibility testing of alpha-hemolytic streptococci

(5) Start Date: 1 Mar 1982	(6) Est Compl Date:
(7) Principal Investigator **Pari L. Morse, DAC** **Clifford Butler, DAC**	(8) Facility: FAMC
(9) Dept/Svc: **Pathology & DCI**	(10) Assoc Investigators: **Paul G. Engelkirk, LTC, MSC** **Robert E. Holcomb, LTC, MSC**
(11) Key Words: **MIC** **alpha-hemolytic streptococci**	
(12) Accumulate MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____
c. Number of subjects enrolled during reporting period: _____
d. Total number of subjects enrolled to date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: _____

(Continue on a separate sheet, designating this continuation as (14)c.)

(15) Study Objective:
To develop a standardized, exceptable method for determining the MIC of alpha-hemoltic streptococci to antibiotics.

(16) Technical Approach:
This study was designed with four phases: 1) development of a modified MIC procedure for alpha-hemolytic streptococci, 2) testing of the modification on standard ATCC control organisms, 3) testing of 100+ alpha-hemolytic streptococci from routine cultures, and 4) further modification for "rough" forms of alpha-hemolytic streptococci.

(17) Progress:
Progress:
Phases 1 through 3 were completed. Unfortunately, the Microbiology Service of the Dept of Pathology has switched to a new type of MIC broth. This protocol has been terminated because the information thus obtained is no longer applicable to MIC testing at FAMC.

DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &
HSPA-I Ltr,
8 July 1982

(1) Date: FY 1984 (2) Protocol WU Nr.: 81-306 (3) Status: Terminated

(4) Title:

Histopathologic and electron microscopic observations of the in vivo interactions between Giardia lamblia trophozoites and the small intestinal mucosa of a variety of small laboratory animals

(5) Start Date: 2 Feb 1982	(6) Est Compl Date: N/A
(7) Principal Investigator Paul G. Engelkirk, LTC, MSC Michael Daly, CPT, MC	(8) Facility: FAMC DCI
(9) Dept/Svc: DCI/Pathology	(10) Assoc Investigators: Dick Wuerz, GS-9
(11) Key Words: Giardia lamblia In vivo interactions Electron microscopy Histopathology	
(12) Accumulate MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of subjects enrolled during reporting period: _____

d. Total number of subjects enrolled to date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: _____

(Continue on a separate sheet, designating this continuation as (14)c.)

(15) Study Objective:

a. To determine whether our laboratory strain of G. lamblia is capable of colonizing intestinal mucosa. b. To establish an animal model for giardiasis. c. To determine the time required for G. lamblia trophozoites to adhere to intestinal mucosa. d. To examine infected mucosa by light microscopy and EM. e. To work out methodology for studying immunized or naturally infected animals.

(16) Technical Approach:

G. lamblia trophozoites were inoculated into ligated small intestinal loops. After varying periods of time, sections of small intestinal mucosa were processed for light and electron microscopy to determine the degree of colonization, and the type and extent of host cell/parasite interaction.

(17) Progress:

Relatively few ligated loop experiments were conducted due to the PCS of the original principal investigator. Of the experiments performed, results were not encouraging. There was a lack of interaction between the inoculated trophozoites and the intestinal mucosa, which could have been due to a variety of reasons. Rather than pursuing this line of investigation, it was felt that a greater amount of information could be gained about human giardiasis by amending and devoting additional manhours to IRC-approved protocol no. 81-304.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/300 (3) Status: Completed

(4) Title: Studies of Immunologically Mediated Thrombocytopenia

(5) Start Date: May 1982	(6) Est Compl Date: April 1984
(7) Principal Investigator: R. Stephen Whiteaker, Ph.D. CPT, MSC	(8) Facility: FAMC
(9) Dept/Svc: DCI/Immunology Svc	(10) Assoc Investigators: Donald C. Corby, COL, MC Jean E. Howard, MAJ, MC
(11) Key Words: thrombocytopenia antiplatelet antibody immune complexes	
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	(13) Est Accum OMA Cost:*

(14) a. Date, Latest HUC Review: May 84 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: 15

d. Total Number of Subjects Enrolled to Date: 32

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To develop an assay to differentiate anti-platelet thrombocytopenia from "innocent bystander" thrombocytopenia.

(16) Technical Approach: Patient serum is mixed with pooled type 0 platelets and platelet adsorable IgG is detected and quantitated using an anti-IgG ELISA procedur .

(17) Progress: , tudy is completed with no complications or problems encountered. A ma ·ipt has been submitted for publication.

(16) Twenty five reproductive age women are to be studied in a double-blind, crossover study to determine the effectiveness of Danazol in premenstrual syndrome. The study is 4 months in duration, 2 months placebo, 2 months Danazol. Patients will take medication from the onset of symptoms to onset of menses. Symptoms will be evaluated with a menstrual symptom diary and results between treatment and placebo cycles will be analyzed statistically. In addition, levels of FSH, LH, progesterone, and estradiol will be obtained and evaluated.

(17) During the fiscal year 1984, significant progress was made in the study. At present, ten patients have completed the study, and an additional ten patients are still on study.

To date, there have been no reported side effects noted. Two patients have voluntarily dropped out of the study due to personal reasons.

It is anticipated that the study will be completed by February 1985 and submitted for publication by May 1985.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/351 (3) Status: Ongoing

(4) Title: Danazol in the treatment of Premenstrual Syndrome.

(5) Start Date: 1 Aug. 83	(6) Est Compl Date: Feb. 85
(7) Principal Investigator: Albert P. Sarno Jr., M.D. Cpt., MC	(8) Facility: FAMC
(9) Dept/Svc: OB/GYN	(10) Assoc Investigators: Edward G. Lundblad, M.D. LTC, MC
(11) Key Words: premenstrual syndrome Danazol	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 20

d. Total Number of Subjects Enrolled to Date: 20

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None

(15) Study Objective: The objective of this study is to perform a prospective double-blind, crossover study to determine if Danazol is more effective than placebo in treating reproductive age women with premenstrual syndrome.

16. PROTOCOL 60: A Phase III Randomized Study of PAC +/- BCG. Four patients entered, all with mild to moderate myelosuppression without sequelae. Ongoing.

17. PROTOCOL 61: A Phase III Randomized Study of Cis-Platinum and Cytoxan Vs Hexamethylmelamine. Ongoing.

18. PROTOCOL 63: A Clinical-Pathologic Study of Stage II-B. Ongoing.

19. PROTOCOL 64: A Randomized Comparison of Rapid Vs Prolonged Infusion of Cis-Platinum. Ongoing.

20. PROTOCOL 66: Ultrastructure of Small Cell Carcinoma. Ongoing.

21. PROTOCOL 70: Randomized Study of Methotrexate and Methotrexate with Citrovorum Rescue. Ongoing.

22. PROTOCOL 72: A, B and C. Ovarian Tumors of Low Malignant Potential. One patient entered. Ongoing.

23. PROTOCOL 73: A Clinical-Pathologic Study of Malignant Melanoma of the Vulva. Ongoing.

24. PROTOCOL 74: Early Stage I Vulvar Carcinoma. Ongoing.

25. PROTOCOL 75: Postoperative Radiation Therapy in Mixed Mesodermal Tumors. Ongoing.

26. PROTOCOL 7601: Ovarian Cancer Study Group Protocol. Closed.

27. PROTOCOL 7602: Ovarian Cancer Study Group Protocol for All Stage I-C and II.
    Section A. Ongoing.
    Section B. Closed secondary to lack of accrual.

28. PROTOCOL 77: A Randomized Comparison of Carboplatin Vs CHIP. Two patients entered without significant response noted; no toxicity noted. Closed.

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Asst Chief, Dept of OB-GYN

(All studies are shown in brief titles, only)

1. PROTOCOL 26:
   - Section A. Master Protocol for Phase II Drug Studies. As on document.
   - Section C. A Phase II Trial of "Cis-Platinum". Closed to all, but first line therapy for uterine sarcomas.
   - Section D. A Phase II Trial of VP16. Ongoing.
   - Section L. A Phase II Trial of Tamoxifen. Ongoing.
   - Section N. A Phase II Trial of DHAD. Ongoing.
   - Section O. A Phase II Trial of AZQ. Ongoing.
   - Section Q. A Phase II Trial of Aminothiadiazole. One patient entered with sustained partial response without significant toxicity. The protocol is now closed.
   - Section R. A Phase II Trial of Progestin. Ongoing.
   - Section S. A Phase II Trial of VM26. Ongoing.
   - Section T. A Phase II Trial of 4'-Deoxydoxorubicin. Ongoing.
2. PROTOCOL 34: A Randomized Study of Adriamycin as an Adjuvant. Ongoing.
3. PROTOCOL 40: A Clinical-Pathologic Study of Stage I and II Uterine Sarcomas. Two patients entered for clinical-pathologic study. Ongoing.
4. PROTOCOL 41: Surgical Staging of Ovarian Cancer. Ongoing.
5. PROTOCOL 44: Evaluation of Adjuvant Vincristine. Ongoing.
6. PROTOCOL 45: Evaluation of Vinblastine, Bleomycin. Ongoing.
7. PROTOCOL 48: A Study of Progestin Therapy and a Randomized Comparison. Ongoing.
8. PROTOCOL 49: A Surgical-Pathologic Study of Women with Invasive Cancer.
   - Section A. Closed.
   - Section B. Ongoing.
9. PROTOCOL 52: A Phase III Study of Cyclophosphamide. Ongoing.
10. PROTOCOL 54: The Treatment of Malignant Tumors of the Ovary with Combination Vincristine, Dactinomycin and Cyclophosphamide. Ongoing.
11. PROTOCOL 55: Hormonal Contraception and Trophoblastic Sequelae. Ongoing.
12. PROTOCOL 56: Randomized Comparison of Hydroxyurea. Ongoing.
13. PROTOCOL 57: Randomized Comparison of Multi-agent Chemotherapy. Ongoing.
14. PROTOCOL 58: A Study of Cytoplasmic Progestin. One patient entered. Closed.
15. PROTOCOL 59: Extended Field Radiation Therapy. Closed.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#:80/350 (3) Status:ongoing (see attached list)

(4) Title:
Gynecologic-Oncology Group Protocols

(5) Start Date: August 1980	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Frank Major, MD Denver General Hospital	(8) Facility: FAMC
(9) Dept/Svc: OB-GYN/GYN-Oncology	(10) Assoc Investigators: GEORGE L PHILLIPS, JR, MD LTC(P), MC Chief, GYN & GYN-Oncology Service Asst C, Dept of OB-GYN
(11) Key Words: Gynecologic-Oncology Group Studies	
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	(13) Est Accum OMA Cost:*

(14) a. Date, Latest HUC Review: 3 Apr 84 b. Review Results: SEE ATTACHED LIST
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

SEE ATTACHED SUMMARY SHEET. Protocols which have been previously delineated as closed as per progress report of 3 Apr 84, have been deleted from the list in their entirety.

(15) Study Objective:
Please see previous report dated 30 Sep 83.

(16) See previous report dated 30 Sep 83.

(17) PROGRESS: See attached list.

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Asst C, Dept of OB-GYN

OB-GYN

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/300 (3) Status: Ongoing

(4) Title: Protein A as an Extracorporeal Immunotherapeutic Treatment for Canine Mammary Adenocarcinoma

(5) Start Date: 1984	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Victor Feuerstein, DAC CPT Ian B. Stewart Nicholas Bethlenfalvay, MD, DAC	(8) Facility: FAMC
(9) Dept/Svc: DCI	(10) Assoc Investigators: T.P. O'Barr, Ph.D., DAC Albert McCullen, CPT(P), VC Donald G. Corby, COL, MC Larry Jones, DAC L. Kramer, SP5
(11) Key Words:	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: To determine the effects of ex vivo plasma perfusion over a protein A bearing gel on naturally occurring canine mammary adenocarcinomas.

(16) Technical Approach: This protocol will evaluate the effects of autologous plasma after circulation through protein A sepharose CL-4B on spontaneous canine mammary adenocarcinomas. Previous literature has reported the ex vivo treatment of plasma with protein A to effectively enhance the host's tumoricidal capabilities. Utilizing this especially pure, standardized and irreversibly bound protein A will eliminate leaching and facilitate the removal of the bound proteins from the gel following perfusion. This will allow the subsequent laboratory analysis of these proteins to establish both identity and quantity.

(17) Progress: To date the study has not been started. The temporary ban on the use of dogs makes uncertain the future supply of dogs.

Publications and Presentations: None

CONTINUATION SHEET, FY 84 ANNUAL PROGRESS REPORT Proto No.: 83/301

Publications and Presentations for FY 84 Annual Progress Report

Publications:

1. Decker, W.J., St. Claire, R.L., III, and Corby, D.G.: Psyllium Mucilloid: A Potential Trapping Agent for Ingested Solvents. International Congress of Clinical Toxicology, August 1982 (Abst).

Presentations:

1. Decker, W.J., St. Claire, R.L., III and Corby, D.G.: Psyllium Muciloid: A Potential Trapping Agent for Ingested Solvents. Presented: 1982 International Congress of Clinical Toxicology, Snowmass, Colorado, August 1982.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/301 (3) Status: Ongoing

(4) Title: Evaluation of Psyllium Mucilloid: A Potential Trapping Agent for Ingested Solvents.

(5) Start Date: 1982	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Donald G. Corby, M.D., COL, MC Walter J. Decker, Ph.D.	(8) Facility: FAMC
(9) Dept/Svc: DCI	(10) Assoc Investigators: A.H. McCullen, DVC, CPT(P), VC
(11) Key Words: psyllium mucilloid ingested solvents	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: To evaluate 1) the stability of P/gel complexes in the GI tract of the laboratory animal, and 2) the ability of P to entrap solvents in vivo thus preventing their absorption and resultant systemic toxic manifestations and/or death.

(16) Technical Approach: The study will be conducted in 4 phases. Phases 1-3 will be experimental subjects (lab animals). The species will be determined from data derived from the literature concerning the known LD50 for ethylene glycol, methanol and kerosene (all commonly found in the home and can be easily swallowed), if available. If data is not available, sutdies of LD50 will be performed. Phase 4 will only be conducted if phases 1-3 show conclusively that P entraps solvents thus reducing systemic absorption, toxicity and death in lab animals. In Phase 4, the subjects will be patients (adult or child) who present for treatment of acute iron intoxication at hospital emergency rooms or who contact poison treatment centers in five states. At that time an addendum covering the exact clinical protocol and human use requirements will be submitted to FAMC and IRC for approval to continue study.

(17) Progress: Studies during the past FY have concentrated on reaffirming LD50 of various solvents in the various animal models. As soon as this preliminary work is completed definite testing with psyllium mucilloid will begin.

CONTINUATION SHEET, FY 84 ANNUAL PROGRESS REPORT Proto No.: 83/300

DEPARTMENT DCI

Progress - continued

administered FeSO4 tablets (650 mg/lb). 30 or 60 min later, the dogs were given Mg)H2 at either 5 or 10X the dose of elemental iron. Serum iron levels in all animals given MgOH2 were significantly lower that those of controls. No significant differences were observed regardless of dose or time of administration of MgHOH2. Although serum Mg++ levels were significantly elevated in all treated animals 4 and 6 hr post iron, no clinical manifestations of hypermagnesemia were observed. These studies demonstrate the effectiveness of MgOH2 in the management of experimental iron intoxication and warrant a clinical trial of its effectiveness in humans.

Publications: Corby, D., Chadwick, E., McCullen, A., and Decker, W.: Effect of Oral Magnesium Hydroxide in Experimental Iron Intoxication. (Abstract, Annual Scientific Meeting, AAPC/AACT/ABMT/CAPCC, San Diego, CA, Oct 7-12, 1984)

Presentations: Corby, DG, et al: Effect of Oral Magnesium Hydroxide in Experimental Iron Intoxication. Presented: AAPC/AACT/ ABMT/CAPCC, Annual Scientific Meeting, October 7-12, 1984 San Diego, California

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/300 (3) Status: Completed

(4) Title: Is $Mg(OH)_2$ (Milk of Magnesia) a Potentially Effective Antidote for Acute Iron Salt Overdose?

(5) Start Date: 1982	(6) Est Compl Date: 30 Sept 84
(7) Principal Investigator: Donald G. Corby, M.D., COL, MC Walter J. Decker, Ph.D.	(8) Facility: FAMC
(9) Dept/Svc: DCI	(10) Assoc Investigators: Elwyn Chadwick, SP6 Albert McCullen, DVC, CPT(P), VC
(11) Key Words: iron salt overdose magnesium hydroxide	
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	(13) Est Accum OMA Cost:*

(14) a. Date, Latest HUC Review: NA b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: To determine the feasibility of administering Milk of Magnesia ($Mg(OH)_2$) suspensions to reduce the absorption of iron salts from the gastrointestinal tract in experimental iron salt intoxication. To determine the optimal time of administration; optimal dose of administration; the temporal limits of effectiveness and potential hazards of this form of therapy.

(16) Technical Approach: The study will be conducted in 3 phases using experimental subjects consisting of laboratory animals. If phases 1-3 show conclusively that $Mg(OH)_2$ is an effective antidote in the treatment of acute iron overdose in the lab animal, phase 4 will be conducted. This phase will consist of subjects (patients adult or child) who present for treatment of acute iron intoxication at hospital emergency rooms or who contact poison treatment centers in five states and have obtained informed consent will be divided randomly into two groups for treatment using conventional therapy and identical treatment.

(17) Progress: We have previously shown that Fe++ and Fe+++ ions readily form complexes with magnesium hydroxide (MgOH2) thus reducing absorption of iron salts from the gastrointestinal tract. However, several questions were previously left unanswered: What is the optimal dose, time of administraiton, optimal limits of effectiveness, and potential hazards of this form of therapy? Dogs were

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/303 (3) Status: Terminated

(4) Title: A Study of Canine and Feline Mammary Tumors: Correlation of Steroid Hormone Receptors of Primary Tumor Sites with those of the Metastases

(5) Start Date: Sep 82	(6) Est Compl Date: Sep 84
(7) Principal Investigator: Albert H. McCullen, DVM, CPT(P)	(8) Facility: FAMC Cell Physiology Svc, DCI
(9) Dept/Svc: DCI/Animal Resources	(10) Assoc Investigators: Leslie C. Kramer, B.S., SP5 John W. Harbell, Ph.D., CPT, MSC
(11) Key Words: Mammary Tumors Steroid Hormone Receptors	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Sep 83 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: To compare steroid hormone receptors in the primary mammary tumors of dogs and cats with receptors found in metastatic lesions, using the autoradiographic technique.

(16) Technical Approach: Samples of tumors and their metastases are minced, placed in culture medium with labeling compound, incubated, then rinsed. Tissue is flash frozen in liquid nitrogen and sectioned in the darkroom into 5 micrometer sections and mounted to previously prepared emulsion-coated slides. Following exposure at -20°, for up to 3 weeks, slides are stained and silver grains over the nuclei of receptor positive cells are counted.

(17) Progress: Work on this project has been terminated as examination of material collected to date is not of diagnostic quality. Further, the temporary ban on the use of dogs makes uncertain the future supply of dogs with tumors.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/302 (3) Status: Ongoing

(4) Title: The evaluation of recently introduced, commercially available clinical microbiology products for possible use in the FAMC diagnostic microbiology laboratory.

(5) Start Date: 1 July 1982	(6) Est Compl Date: 1 July 1985
(7) Principal Investigator: Pari L. Morse, DAC Clifford Butler, DAC	(8) Facility: FAMC
(9) Dept/Svc: Dept of Pathology/DCI	(10) Assoc Investigators: Paul G. Engelkirk, LTC, MSC J.T. Stocker, LTC, MC
(11) Key Words: Diagnostic microbiology Microbiological products	
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	(13) Est Accum OMA Cost:*

(14) a. Date, Latest HUC Review: Jul 84 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: N/A

d. Total Number of Subjects Enrolled to Date: N/A

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate recently introduced products which are of interest to the Microbiology Section, Dept of Pathology, FAMC, but which cannot adequately be evaluated within that laboratory due to time, personnel, and monetary constraints. This evaluation will include cost effectiveness, ease of use, reproducibility and speed.

(16) Technical Approach: A separate protocol will be designed for each product evaluated.

(17) Progress: There was no progress on this protocol during FY 1984, due primarily to a shortage of personnel in the Microbiology Section, Dept of Pathology. Several ideas are being discussed, and some new products will be evaluated during FY 1985.

DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &
HSPA-I Ltr,
8 July 1982

(1) Date: FY 84 (2) Protocol WU Nr.: 82/301 (3) Status: Completed

(4) Title:

The Antigenic Evaluation of Axenically-Cultivated Giardia lamblia.

(5) Start Date: 1 July 1982 (6) Est Compl Date: 1 July 1984

(7) Principal Investigator

Victor Feuerstein DAC,DCI

(8) Facility: FAMC

Biochemistry Service

Immunology Service
Microbiology Service

(9) Dept/Svc: DCI, FAMC

(10) Assoc Investigators:

P.G. Englekirk, Ph.D., LTC,MSC.
T.B. Brewer,M.D.,MAJ,MC.
R.S. Whiteaker, Ph.D.,CPT,MSC.

(11) Key Words:

Giardia
Antigenic

(12) Accumulate MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: ~~1 July 83~~ b. Review Results: continued

c. Number of subjects enrolled during reporting period: NA

d. Total number of subjects enrolled to date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: NA

(Continue on a separate sheet, designating this continuation as (14)e.)

(15) Study Objective:

To ellucidate and immunologically characterize the antigenic make-up of the trophozoites of axenically-cultivated Portland and NIH strain Giardia lamblia.

(16) Technical Approach: Following mechanical, chemical or immunological separation into components; double diffusion, electrophoretic, iso-electric and chromatographic analysis will be utilized to isolate and characterize individual moieties.

(17) Progress: As many as thirty individual antigen moieties have been separated. The specific techniques have been refined. An inate time-related lability for many of the antigens has been characterized, as well as the extremely weak nature of the antigens isolated be these procedures. The characteristics of the antigens isolated make any future work with stimulation of specific cell populations in culture prohibitive, Additionally, the inability to separate strains of the parasite by these highly sophisticated and sensitive assays suggests the need to look at the encysted stage of the parasite.

(2)

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/350 (3) Status: ongoing

(4) Title: "A Prospective Study of the Effects of CO2 Laser Vaporization of the Cervix for Cervical Intraepithelial Neoplasia on Cervical Factors and Subsequent Fertility."

(5) Start Date: 1 Aug 84

(6) Est Compl Date: 31 Jul 86

(7) Principal Investigator:
GEORGE L PHILLIPS, JR, MD
LTC(P), MC
Chief, GYN & GYN-Oncology Service
Asst C, Dept of OB-GYN

(8) Facility: FAMC
GYN-Oncology Service

(9) Dept/Svc: Dept of OB-GYN/

(10) Assoc Investigators:
EDWARD G LUNDBLAD, MD
LTC,MC
Chief, Family Planning Service

(11) Key Words:
CO2 Laser Vaporization
Cervical Intraepithelial Neoplasia
Vertility Effects

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: one (1)

d. Total Number of Subjects Enrolled to Date: one (1)

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". No adverse effects have been noted.

(15) Study Objective: To assess the impact, if any, of CO2 laser vaporization of the cervix for cervical intraepithelial neoplasia upon cervical factors related to potential fertility and subsequent fertility impact, if any.

(16) TECHNICAL APPROACH: Patients with the diagnosis of CIN who are candidates for laser vaporization of the cervix will undergo pre- and postvaporization postcoital tests and long-term follow-up of fertility.

(17) PROGRESS: Only one patient has been entered on this study since its inception. This, in a large part, is due to the lack of a suitable smoke evacuation device in the area where the CO2 laser is operated. This device has been approved and should be received shortly. It is anticipated that accrual will increase following receipt of this device.

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PEDIATRICS

DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &
HSPA-I Ltr,
8 July 1982

(1) Date: FY84 (2) Protocol WU Nr.: 81/402 (3) Status: Terminated

(4) Title:
Diagnosis of Respiratory Syncytial Virus (RSV) Infection in Infants by Enzyme-Linked Immunosorbent Assay (ELISA)

(5) Start Date: 7 January 1981 (6) Est Compl Date: N/A

(7) Principal Investigator
Donald R. Moffitt, MAJ, MC
Donald D. Paine, GS-11

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics/DCI

(10) Assoc Investigators:
William H. Parry, COL, MC
Paul G. Engelkirk, LTC, MSC

(11) Key Words:
ELISA
RSV infection

(12) Accumulate MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of subjects enrolled during reporting period: _____

d. Total number of subjects enrolled to date: 53

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: _____

(Continue on a separate sheet, designating this continuation as (14)e.)

(15) Study Objective: Development of an ELISA procedure for the detection of RSV antigen using commercially available reagents, and determination of the efficacy of the procedure for the diagnosis of RSV infections in infants.

(16) Technical Approach: An ELISA procedure will be developed using commercially availab reagents and virus controls. Nasal secretions and urine specimens will be obtained fro infants with suspected RSV infection, and urine specimens will be obtained from control children. These specimens will be tested by the ELISA procedure.

(17) Progress:
To date, a total of 18 inpatients have been entered into this study. Urine and nasal ELISA procedures for the detection of RSV antigen have been performed on urine and nasal specimens from these patients. In addition, ELISA procedures have been performed on urine specimens from 35 control children. This protocol is being terminated due to the low number of RSV patients available for entry into this studyand unresolved irregu larities in the assay procedure for urine specimens. The number of RSV patients was far lower than anticipated at the outset of the study, and is too small for valid statistical analyses.

Incl 1

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/400 (3) Status: Ongoing

(4) Title: The Effect of Glycerin Suppository Administration On Bilirubin Levels in Infants Receiving Phototherapy

(5) Start Date: October 1982

(6) Est Compl Date: October 1984

(7) Principal Investigator:

Gail Murphy, M.D.
CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatric/Newborn

(10) Assoc Investigators:

John R. Pierce, M.D., LTC, MC
Gerald B. Merenstein, M.D., COL, MC

(11) Key Words:
Hyperbilirubinemia
re: glycerin suppositories

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Mar 83 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: None

d. Total Number of Subjects Enrolled to Date: None

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective: To determine whether the utilization of glycerin suppositories to enhance stooling effects peak serum bilirubin or influences changes in bilirubin levels in infants 36 weeks gestational age being treated with phototherapy for hyperbilirubinemia.

(16) Technical Approach: Sixty infants 36 weeks gestation and 1 week of age who require phototherapy for treatment of hyperbilirubinemia will be studied. Infants will be randomly assigned to a treatment group of glycerin suppositories every 4 hours or a control group Bilirubin levels will be determined every 6-8 hours while under phototherapy for treatment and control patients. Results will be tabulated and statistically evaluated for any benefit.

(17) Progress: Due to heavy clinical and research work load, no patients are yet enrolled. However, enrollment is anticipated in the near future.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: FY 84 (2) Protocol WU#: 82/401 (3) Status: Completed

(4) Title: Modified Immune Serum Globulin In Neonates.

(5) Start Date: 1 Apr 82	(6) Est Compl Date: 30 Sep 83
(7) Principal Investigator: John R. Pierce, M.D. LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Pediatric/Newborn	(10) Assoc Investigators: Gerald W. Fischer, M.D. LTC, MC
(11) Key Words: Modified immune serum globulin, kinetics, neonates	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 15

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None.

(15) Study Objective: To analyze the ability of Modified Immune Serum Globulin (MISG) to elevate neonatal IGG levels. We will specifically look at pre and post MISG serum for evidence of increased activity against Group B streptococcus using invetro assays for opsonic antibody.

(16) Technical Approach: Infants will be assigned to the control or treatment group. The treatment group will receive an infusion of MISG given over 4-8 hours. Blood samples will be drawn prior to and following the infusion at specific intervals. Sera will be forwarded to the Uniformed Services University of the Health Sciences in Bethesda, Maryland for all determinations. Infants will be monitored closely during the infusion for any side-effects or adverse reactions.

(17) Progress: This protocol was a cooperative protocol between several of the Army Medical Centers. The study has been completed by the addition of patients from the other medical centers. It was not necessary during this past calendar year to enroll any new patients here at Fitzsimons in this protocol.

Publications and Presentations: None

DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &
HSPA-I Ltr,
8 July 1982

(1) Date: FY Sep 30, 82 (2) Protocol WU Nr.: 82/403 (3) Status: Ongoing
(4) Title: POG Studies

(5) Start Date: Oct 1981 (6) Est Compl Date: 1986
(7) Principal Investigator (8) Facility: FAMC
Askold D. Mosijczuk, LTC, MC

(9) Dept/Svc: Pediatrics
(10) Assoc Investigators:
Thomas Carter, COL, MC Neursurgery Service
Jeffrey Clark, COL, MC, C, Surgery Service
William Daniel, M.D., Radiation Oncology
Vishnu Reddy, LTC, MC, C, Hematopathology
Thomas Stocker, LTC, MC, C, Ped Pathology

(11) Key Words:
POG Studies

(12) Accumulate MEDCASE:*
(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Oct 83 b. Review Results: Continue study
c. Number of subjects enrolled during reporting period: 7
d. Total number of subjects enrolled to date: 16
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet, designating this continuation as (14)e.)

(15) Study Objective: See attached sheet

(16) Technical Approach: See attached sheet

(17) Progress: See attached sheet

SUMMARY OF PROTOCOL PROGRESS

2. PROBLEMS ENCOUNTERED:

A. Fitzsimons' participation in POG protocols was audited by Dr. Trueworthy, Ped Oncologist from Kansas University and Chris Blevin, Data Manager, from Los Angeles as part of an NCI directive to all POG intitutions to insure compliance with NCI guidelines involving research studies in cancer patients. Our compliance with data management requirements on POG protocols was excellent. Two problems, however, were found in the audit. (1) lack of documentation of having obtained consent forms for 3 patients enrolled on POG studies between 1980 and 1982, and (2) lack of documentation by our IRB officials that a Cooperative Group Assurance Policy was in effect regarding POG studies. Both problems have been addressed and corrected.

ENCLOSURERS:
(1) copy of POG Audit Findings
(2) copy of memorandum Aug 6, 1984.

3. MODIFICATION OF PROTOCOL DESIRED:

See attached list of Revisions, Addendums, modifications which have occurred in the last fiscal year.

4. (a) Adverse reactions - no unusual reactions to chemotherapy, surgery or radiation therapy have been encountered. Myelosuppression secondary to chemotherapy has been severe on occasion, but not unexpected. Myelosuppression has been reversible in all cases.

(b) Kinds and number of subjects enrolled:
There have been 16 children enrolled

PT Initials	DIAGNOSIS	POG STUDY
L. P.	melanoma	Rare Tumor Reg 7799
J.H.	ALL	ALINC #13 8035/36
J.P.	ALL	8035/36
A.D.	sarcoma	Rare Tumor Reg 7799
D.I.	ALL	8035/36
C.B.	ALL	ALINC #13 8035/36
S.K.	ALL	8035, 7837
D.D.	histiocytosis X	Natural study 7376
F.B.	rhabdomyosarcoma	IRS II
D.W.	medulloblastoma	MOPP/vsRT 7909
D.B.	neuroblastoma	8104/05
M.P.	ependymoma	7621
R.O.	rhabdomyosarcoma	8157
R.H.	histiocytosis X	7376
K.C.	rhabdomyosarcoma	7898
N.D.	aggressive fibromatosis	7799
D.W.	osteosarcoma	8107

4. (c) On ALINC #13 (POG 8035/36) all FAMC patients have achieved complete remission status and none have relapsed to date; however time on study is extremely short as of this date. Pt initials F.B. with rabdomyosarcoma on POG 7898 completed therapy in Jul 83 and continues in CR. Pt. D.W. with medulloblastoma on POG 7909 completed in Aug 83 and continues in CR. Patient D.B. with neuroblastoma on 8104/05 achieved PR, relapsed and died. Pt M.P. with ependymoma on 7621 developed progressive disease while on protocol; was later taken off study and subsequently died. Pt. R.O. with Stage IV rabdomyosarcoma on 8157 achieved CR; subsequently relapsed, was taken off study, treated with alternate chemotherapy but progress and died. Pts R.H. and D.D. with histiocytosis X on 7376 both achieved CR and are currently disease free. Pt K.C. with rhabdomyosarcoma on 7898 is alive in PR. Pt. M.D. with aggressive juvenile fibromatosis on 7799 is alive in CR. Pt L.P. with melanoma of the eye on 7799 is alive in CR. Pt A.D. with congenital undiffereniated sarcoma on 7799 achieved PR with VAC chemotherapy but soon progress and died. Pt D.W. with metastatic osteosarcoma on 8107 showed no response to T-12 a regimen chemotherapy and has progressive metastatic disease.

4. (d) Significant results are as follows:

MOPP vs rad therapy alone for medulloblastoma. Pts randomized to MOPP arm are showing much better survival than those treated with the radiation therapy alone arm. Difference is approaching statistical significance.

Pts with metastatic rhabdomyosarcoma on 8157 - although most patients showed an excellent initial response to total body irradiation (TBI) and aut bone marrow transplant, all have subsequent relapsed and died. Study will soon be closed.

Pts with rhabdomyosarcoma on IRS II 7898 continue to show good overall survival, especially those with head and neck and GU primaries. The addition of adriamycin for advanced stage disease has not increased response rates or survival as compared to VAC chemotherapy. IRS III will soon be opened which will look at the possible benefit of VP 16 and cis-platinum chemotherapy in advanced stage rhabdomyosarcoma.

POG 8035 - classification of ALL -it appears that there is a certain subtype of null cell CALLA positive ALL which is also positive for cytoplasmic IGM. This subtype is called pre-B cell ALL. Thus far, patients with this subtype have not fared as well on ALINC #13 treatment protocol (POG 8036) as other children with CALLA positive null cell ALL on this protocol.

(e) Current risk of therapy appear to be acceptable in light of the response rate and quality of life achieved by pts on POG studies, both at FAMC and group wide.

(f) Refer to (4d).

(g) Consent forms are still sufficient to the best of my judgment. Judgment regarding the legal sufficiency of the consent forms is deferred to JAG.

DETAIL SUMMARY SHEET

14. (e) None.

15. POG studies can be divided into two basis types:
(1) Therapeutic studies- Objective is to develop improved treatment modalities for a variety of pediatric malignant tumors.
(2) Non-therapeutic studies- Objective is to further study the biology of a variety of pediatric tumors. This is accomplished by obtaining various specimens of the tumor and other lab data which is then forwarded to central reference laboratories.

16. Technical Approach: Various laboratory data pertaining to the patient malignant tumor is obtained which is forwarded to central reference labs and to a central POG Statistical Office. This data is used to increase basic knowledge regarding these tumors and is also utilized to stratify patients to various prognostic subgroups. After stratification, patients are randomly assigned to one of 2 or 3 treatment modalities. The response rate to treatment and individual data is compared among different treatment regimens. In addition, long term survivors are monitored for several years after completing therapy for possible long term effects of therapy.

17. PROGRESS: Since the last review by DCI in Oct 83, the following specific protocols under the heading "82-403 POG Studies" have been closed to new patient entry. B(c)89#1 POG 7376, , B(c)89#2 POG 8047, B(c)89#3 POG 7896, B(c)89#4 POG 7895, B(c)89#5 POG 8095, B(c)89#12 POG 7712, B(c)89#15 POG 7612.

The following protocol has not been activated at FAMC at Principal Investigator's request. B(c)89#7 which is POG 8103 entitled Hepatoma III.

The following protocols have been recently approved and should be added to "82-403 POG Studies" and this is POG 8303 SIMAL #3, pOG 8304 SIMAL #4, POG 8305 SIMAL Lab Subclassification.

NOTE: First 20 studies have been reported on in August 1984
This additional report to concerns itself with B(c) 89 #21, 22, 23,24

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/403 (3) Status: OnGoing

(4) Title: 24 Orig POG/SWOG Studies (FAMC DCI B(c) 89 Series

(5) Start Date: Nov 1982	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Askold D. Mosijczuk, M.D.,LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Pediatrics	(10) Assoc Investigators: Thomas Carter, COL, MC Neurosurgery Svc Jeffrey Clark, COL, MC, C, Surg, Svc William Daniel, MD, Radiaton Oncology Vishnu Reddy, LTC, MC, C, Hematopathology Thomas Stocker, LTC, MC, C, Ped. Pathology
(11) Key Words:	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: Continue Study

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: and (16) Technical Approach are continued in the protocol for the 24 POG/SWOG studies involved under WU #82/403.

(17) Progress

Protocol B9c)89 #24 - POG 8156 Live Varicella protocol has been recommended for termination at FAMC on 25 April 1983. No patients have been enrolled at FAMC on this study.

In April 1983 the following 3 POG protocols were approved by IRB and should be added to "82/403 Orig POG/SWOG Studies"

1. POG 8303-SIMAL #3 (B104)
2. POG 8304-SIMAL #4 (B105)
3. POG 8305-SIMAL LAB Subclassification (B106)

To date (19 Sep 84) no patients have as yet been enrolled into these 3 studies at FAMC.

DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &
HSPA-I Ltr,
8 July 1982

(1) Date: FY 84 (2) Protocol WU Nr.: 83/400 (3) Status: Terminated

(4) Title: A Comparative Study of Body Temperature Measured at Different Sites in Very Low Birth Weight Infants.

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator M. Gail Murphy, CPT, MC	(8) Facility: FAMC
(9) Dept/Svc: Pediatrics	(10) Assoc Investigators:
(11) Key Words: Temperatures, VLBW infants	LTC John R. Pierce, M.D., MC

(12) Accumulate MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____
c. Number of subjects enrolled during reporting period: _____
d. Total number of subjects enrolled to date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: _____

(Continue on a separate sheet, designating this continuation as (14)c.)

(15) Study Objective:

(16) Technical Approach:

(17) Progress:

Protocol terminated because it has been completed and published by another investigator.

FAMC A.P.R. (RCS MED 3-0) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 83 (2) Protocol WU#: 83/401 (3) Status: Ongoing

(4) Title: Prevalence of Endometriosis Externa in Adolescent Women Complaining of Severe Dysmenorrhea

(5) Start Date: 4 April 1983 (6) Est Compl Date: June 1986

(7) Principal Investigator
Mark E. Blaedel, LTC, MC
Edward Lundblad, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics/OB-GYN

(10) Assoc Investigators

Jerald F. Dirks, Psy D.

(11) Key Words:

Endometriosis
Dysmenorrhea

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA Review Results: NA

c. Number of Subjects Enrolled During Reporting Period:

Stage I	700
Stage II	66
Stage III	3

d. Total Number of Subjects Enrolled to Date: Same

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective:

1. An epidemiologic survey of young women will document the prevalence of symptomatic endometriosis externa in a middle class primary care population of adolescent women complaining of dysmenorrhea. This prevalence figure will tell the health care provider how alert he has to be to this condition.

2. Background biosocial data will be collected in hopes that certain distinctive historical markers will distinguish the young woman with secondary dysmenorrhea due to endometriosis from the patient with severe primary dysmenorrhea.

3. A registry of young women with endometriosis will be developed. In the future, trials of medication can be given to these young women to determine the therapy of greatest benefit. These women can also be followed for a prolonged period of time to determine the incidence of complications of endometriosis.

(16) Technical Approach: This retrospective stage of epidemiologic survey is designed to isolate by questionaire those young women who might have endometriosis and subject them to laparoscopy.

(17) Progress: As of 30 September 1984, approximately 700 patients have completed the Stage I questionnaire. Out of these approximately 60 have completed the Stage II requirements and, to date, three patients have had a laparoscopy.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/402 (3) Status: Ongoing

(4) Title: B2-Microglobulin as a Measure of Renal Tubular Function in the Neonate

(5) Start Date: 11/1/83	(6) Est Compl Date: 8/85
(7) Principal Investigator: Ronald J. Portman, M.D. MAJ MC USA	(8) Facility: FAMC Children's Hospital at Washington University St. Louis, MO.
(9) Dept/Svc: Pediatrics/Newborn	(10) Assoc Investigators: John R. Pierce, M.D. LTC MC USA Alan M. Robson, M.D. Director Pediatric Renal Division in St. Louis Michael Southgate, M.D. CPT MC USA Rosie Gibbons CPT ANC
(11) Key Words: B2-Microglobulins Intrauterine Distress Renal Tubular Function	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 49
d. Total Number of Subjects Enrolled to Date: 49
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The purpose of this study is to examine the renal handling of this low molecular weight protein at various gestational and postpartum ages in neonates who manifest evidence of normal or abnormal intrauterine environments (e.g., infants of diabetic mothers, small for gestational age infants, prolonged rupture of membranes, meconium stained amniotic fluid, and history of maternal drug abuse).

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 74/651 (3) Status: Ongoing

(4) Title: Establishment of and Training in Methods for Special Studies of Abnormal Hemoglobins

(5) Start Date: January 1974	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Nicholas C. Bethlenfalvay, M.D., DAC	(8) Facility: FAMC
(9) Dept/Svc: Primary Care	(10) Assoc Investigators: Joseph Lima, DAC T. Waldrup, DAC
(11) Key Words: Abnormal Hemoglobins Techniques on Identification	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 12/82 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective:
To establish and conduct training in methods for special studies of abnormal hemoglobins.

(16) Technical Approach: To acquaint and to train existing personnel in the performance of various procedures as they pertain to biochemical study of hemoglobins and red cell enzymes involved in hemoglobin function.

(17) Progress: Since 1974 the following can now be performed. Column chromatography; electrophoresis and iso-electrofocusing of hemoglobin; column chromatography and electrophoresis and iso-electrofocusing of globin and electrophoretic demonstration of iso-enzymes of both NADH and NADPH dependent methemoglobin reductases. Quantitation of NDAH-cytochrome b_5 and HADPH MR, glutathione, glutathione reductase now can be done. G-6 PD iso-enzyme patterns now can be determined. Recently equipment for the determination of hemoglobin oxygen dissociation curve has been obtained, and is operational. Carbohydrate and nucleoside utilization of red cells can now be assessed using cold or radioactive substrates.

In FY84, the following was accomplished: quantitation of erythrocyte glycolytic intermediates, electrofocusing and electrophoresis of adenosine deraminase and of purine nucleoside phosphorylase.

PRIMARY CARE AND COMMUNITY MEDICINE

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/600 (3) Status: Ongoing

(4) Title:
Prospective Study of the Effects of Diagnostic Ultrasound on the Human Auditory Mechanism Following in Utero Exposure

(5) Start Date: February 1984	(6) Est Compl Date: June 1986
(7) Principal Investigator: Marlene J. Severson, M.D., CPT, MC Gloria Hubred Komppa, M.D. Jeffrey Davies, PHD, CPT, MSC Fred Garner, M.D., CPT, MC James Potter M.D., CPT, MC	(8) Facility: FAMC
(9) Dept/Svc:Radiology/Ultrasound	(10) Assoc Investigators: Nasser Ghaed, M.D., COL, MC John Kolmer, M.D., COL, MC
(11) Key Words: Diagnostic Ultrasound, Biological Effects, Human Auditory Mechanism	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:Approximately 150

d. Total Number of Subjects Enrolled to Date:Approximately 150

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A

(15) Study Objective:
To determine whether children exposed (to diagnostic ultrasound) in utero have detectable hearing loss as compared to a non exposed population.

(16) Technical Approach: Pregnant women are being ramdomized into two groups. The control group is not receiving obstetric ultrasound. Family, birth and post natal histories are being collected on all study participants. Ultrasound data is collected on all women receiving it. Three to four months following delivery, the infants will be examined and audiological tests performed. The data will be compared.

(17) Progress: In the fiscal year 1984, obstetric ultrasound data has been collected on approximatley 150 patients. None have had post natal hearing testing to date. Approximately five low risk pregnant women are currently enrolled in our control group. One has delivered approximatley one month ago. ENT examination and audiological testing should begin in approximately two to three months. Selection of the control group and collection of ultrasound data will continue.

PRESENTATIONS/PUBLICATIONS: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/601 (3) Status: Ongoing

(4) Title: Evaluation of Indium Oxine In-111 Labeled Cellular Blood Components

(5) Start Date: 1 Oct 83	(6) Est Compl Date: 1985
(7) Principal Investigator: Peter W. Blue LTC, MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words: Indium Oxine	Nasser Ghaed COL, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 11/83 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None.

(15) Study Objective:

To evaluate Indium Oxine Labeled Blood Components and their metabolic fate, currently labeled WBC in infection.

(16) Technical Approach:

Blood components (currently WBC) are removed from patient, labeled, reinjected, and patient is scanned (labeled WBC will localize the infection sites).

(17) Progress: Two abnormals.
Six normals.
Test is useful.

Presentations/Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/602 (3) Status: Ongoing

(4) Title: Gallium Index: Qualitative vs. Quantitative Analysis

(5) Start Date: July 1983	(6) Est Compl Date: 1985
(7) Principal Investigator: Peter W. Blue LTC, MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators: Nasser Ghaed COL, MC
(11) Key Words: Gallium Index	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 11/83 b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 30
d. Total Number of Subjects Enrolled to Date: 30
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None.

(15) Study Objective:
To evaluate a computer quantitative assessment of gallium uptake in normal and abnormal lungs and compare it to a previously used qualitative method.

(16) Technical Approach:
All gallium studies are acquired on computer and pulmonary functions acquired. The gallium index is calculated both ways (vide supra) and when enough patients seen, data analyzed.

(17) Progress:
Data collection in progress. Results pending.

Presentations/Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 32/C01 (3) Status: Completed Jan 84

(4) Title:

Effects on the Human Auditory Mechanism Following In Utero Exposure to Diagnostic Ultrasound

(5) Start Date: 11/82	(6) Est Compl Date:
(7) Principal Investigator: Gloria H. Komppa, M.D., C, Diagnostic Ultrasound Section; Marlene Severson, M.D., CPT, MC, US Army, Jeffrey Davies PHD., CPT, MC, US Army	(8) Facility: FAMC
(9) Dept/Svc: Radiology, ENT	(10) Assoc Investigators: Nasser Ghaed, M.D., COL, MC, C, Dept of Radiology; John Kolmer, M.D., LTC, MC C, Dept of ENT
(11) Key Words: Ultrasound, In Utero, Hearing	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: Approx 100, 22 tested

d. Total Number of Subjects Enrolled to Date: Approximately 100

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None

(15) Study Objective:

To determine whether children exposed in utero have detectable hearing loss as compared to a normal polulation.

(16) Technical Approach: The auditory test results of approximately 100 children, exposed to ultrasound in utero, were to have been compared to approximately 30 nonexposed children.

(17) Progress: A normal control group of children not exposed to ultrasound was not successfully obtained. The results of the hearing tests performed on the exposed children were reviewed. All results were within normal limits but skewed to one end of the expected bell shaped curve. A prospective study was initiated (see work unit NR 84/600).

PRESENTATIONS/PUBLICATIONS: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 80/602 (3) Status: Ongoing

(4) Title:
I.V. administration of 131-I-6-B iodomethylnorcholesterol (NP-59) for adrenal evaluation and imaging.

(5) Start Date: 1980 | (6) Est Compl Date: Indefinite

(7) Principal Investigator:
Peter W. Blue LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Nuc Med Svc

(10) Assoc Investigators:
Nasser Ghaed COL, MC

(11) Key Words:
iodocholesterol
adrenal

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 11/83 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 1

d. Total Number of Subjects Enrolled to Date: 3

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None.

(15) Study Objective:

Clinical evaluation of NP-59 as a diagnostic agent for the detection of adrenal cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla.

(16) Technical Approach:

Each patient will be studied while taking Lugol's or SSKI to protect the thyroid. Some patients will have adrenal function suppressed with Dexamethasone. Following a 2 millicure dose of NP-59, each patient will be scanned at day 3 and possibly day 5 and 7.

(17) Progress:

One patient evaluated with normal results. Test helpful.

Publications/Presentations: None.

RADIOLOGY

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#:84/403 (3) Status: Ongoing

(4) Title: Hypercalciuria in Children with Isolated Hematuria.

(5) Start Date: 1984

(6) Est Compl Date: January 1986

(7) Principal Investigator:
Ronald J. Portman, MD, MAJ, MC

(8) Facility: FAMC
University of Colorado Health Science Center
Southwest Pediatric Nephrology Group

(9) Dept/Svc: Pediatrics/Nephrology

(10) Assoc Investigators:
Gary M. Lum, Renal Division, University of Colorado Medical Center

(11) Key Words:
hypercalciuria
hematuria

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: To determine the incidence of hypercalciuria in children presenting with isolated gross or microscopic hematuria. To determine if hypercalciuria is due to a) idiopathic renal calcium wasting, b) intestinal hyperabsorption of calcium or c) hyperparathyroidism.

(16) Technical Approach: Patients who are found to have hematuria, but without protein in the urine, will have a twenty-four hour urine collection for calcium excretion and a blood test for calcium. If these studies are normal, no further studies will be performed. If the calcium secretion is abnormal, the patient will be placed on a specific low calcium diet for one week and then another twenty-four hour urine collection for calcium repeated. After this is completed, the child will have a calcium challenge test consisting of an orai calcium supplement and a specific breakfast high in calcium. Four hour urine collections will follow this calcium load and a blood test for parathyroid hormone levels. Also, an intravenous pyelogram will be obtained to be sure the patient does not have kidney stones or other urinary tract abnormalities.

(17) Progress: Study is new, so no progress as of this date.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/402 (3) Status: Ongoing

(4) Title:

Hypertension in adolescents

(5) Start Date: 1 sept 1984	(6) Est Compl Date: 30 May 1985
(7) Principal Investigator: Victor I. Lugo-Miro, M.D. Captain, MC.	(8) Facility: FAMC
(9) Dept/Svc: Peds/ Adolescent Med	(10) Assoc Investigators: Ronald J. Portman, M.D.,MAJ, MC. Mark Blaedel, M.D., LTC, MC. Robert Slover, M.D., MAJ MC.
(11) Key Words: Hypertension Adolescents	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 426

d. Total Number of Subjects Enrolled to Date: 426

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A

(15) Study Objective:

Establish the best measure of normal and abnormal blood pressure in children based on age, height, weight and body mass indices.

(16) Technical approach:

In our study we will meassure height, weight and blood pressure on all the adolescents that will visit our clinic. We will calculate ponderosity index and then establish if the patient is hypertensive or not by values from previous studies. At the end we will be able to establish our own normal values and will identify what is the best determinant for blood pressure (Ht, Wt, Ponderosity, etc.)

(17) Progress:

We have been able to take all meassurements in 426 patients with an initial yield of 11% of the patients showing hypertensive readings based on The Bogalusa Heart Study 95th percentile value for systolic and diastolic blood pressure. Those patients have been followed up by us for a second and third blood pressure determination and those who keep showing hypertension will be fully evaluated to establish their pertinent diagnosis. These number of patients (50 in total) made possible for us to establish a hypertension clinic for the evaluation mentioned above.

Our preliminary data is also sugesting the relationhsip of height and ponderosity index as the best determinants for blood pressure development but it is however too early for drawing any conclusions.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 84/401 (3) Status: Ongoing

(4) Title:

Neonatal Xanthine and Aminoglycoside Kinetics.

(5) Start Date: May 1984	(6) Est Compl Date: June 1985
(7) Principal Investigator: M. Gail Murphy, M.D., CPT, MC	(8) Facility: FAMC
(9) Dept/Svc: Pediatrics	(10) Assoc Investigators: Gerald B. Merenstein, M.D., COL, MC John R. Pierce, M.D., LTC, MC
(11) Key Words: Computer program Drug kinetics	
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	(13) Est Accum OMA Cost:*

(14) a. Date, Latest HUC Review: First b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 21 patients

d. Total Number of Subjects Enrolled to Date: 22

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None.

(15) Study Objective: To employ a Bayesian computer program to individualize xanthine and aminoglycoside drug dosing decisions.

(16) Technical Approach: Sixty infants in nursery who require xanthine or aminoglycoside therapy will be studied. Dosing decisions based on program predictions of pharmacokinetics will be analyzed for prediction accuracy.

(17) Progress: 21 preliminary patients receiving gentamicin have been studied. The computer predictions have made therapeutic decisions quicker and more accurate.

Presentations: Murphy, M.G. & Peck, C: Revisions of gentamicin therapy with a Bayesian Program. Presented: Aspen Conference on Perinatal Research, Aspen, CO, July, 1984.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/403 (3) Status: Terminated
(4) Title: Myelography in Medulloblastoma

(5) Start Date: November 1983	(6) Est Compl Date:
(7) Principal Investigator: Askold D. Mosijczuk, M.D., LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Pediatrics	(10) Assoc Investigators:
(11) Key Words: Myelography in Medulloblastoma	Daniel McNeil, LTC, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:
Assess the potential benefit of metrizamide CT scan of the spine following metrizamide myelography in detecting spinal metastases due to medulloblastoma.

16. Technical Approach:
As described in protocol

17. Progress:
No patients have been entered on this study at FAMC since patients with newly diagnosed or recurrent medulloblastoma have been admitted to our institution in the past 10 months. Other Army medical centers (WRAMC, BAMC, TAMC, LAMC) have either not had any eligible patients for this protocol or for other reasons have not entered patients into this study. For these reasons, I request that this protocol be terminated.

Publications and Presentations: None

PUBLICATIONS for FY 84 Annual Progress Report Proto No. 83/402

SERVICE Newborn/Ped. Nephrology Sec. DEPARTMENT Pediatrics

(1) Portman, R.J., Cole, J.W., Perlman, J.M., Yin, L., and Robson, A.M.: Tubular Dysfunction in Infants with Meconium Stained Amniotic Fluid-Diagnosis Using B2-Microglobulin. Ped. Res. 18:341A 1984

(2) Cole, J.W., Portman, R.J., Lim, Y., Perlman, J.M., and Robson, A.M. Urinary Beta-2-Microglobulin in Full Term Mewborns: Evidence for Proximal Tubular Dysfunction in Infants with Meconium Stained Amniotic Fluid Submitted for publication to Pediatrics

PRESENTATIONS:

(1) Portman, R.J., Cole, J.W., Perlman, J.M. Lim, Y., and Robson, A.M. Tubular Dysfunction in Infants with Meconium Stained Amniotic Fluid-Diagnosis Using B2 Microglobulins. Presented at the Society for Pediatric Research, San Francisco, CA May, 1984.

(2) Portman, R.J.: Tubular Dysfunction in Neonates Diagnosed by the Urinary Concentration of B2 Microglobulins. Presented to the Aspen Conference on Military Perinatal Research, Aspen, CO, August 1984.

16. Patients are selected on admission to the newborn nursery for either the normal group or for a specific pathologic condition. After consent is obtained, a urine bag is placed and urine collected for creatinine and B2M determinations. Blood is obtained at the routine four hour hematocrit heel stick for the same determinations. This is repeated with the urine collection on days 3 and 14 of life at the time of PKU determinations. Creatinine is performed by the routine chemistry lab and B2M by the RIA lab. Data will be analyzed on the NOAA computer/MISS system.

17. Fourty-nine newborns have been enrolled in the study in fiscal year 1984. No complications have been noted from the urine bags nor the heelstick procedures. There were no problems in obtaining consent for the study. The patients included 27 normal infants, nine with meconium stained amniotic fluid, three with acute tubular necrosis, amd nine with various other processes. The major difficulty with the study was obtaining all four pieces of data on three different occasions which occurred only in three patients. The normal urinary B2M for our 27 patients was 0.6 mg/l on day one and 1.6 mg/l on day three of life. Not enough numbers were obtained in the ather groups as yet to show any significant trends except for the ATN which had a mean value on the first day studied 12.7 mg/l indicative of marked tubular dysfunction. Request approval of this protocol and its modification.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 78/650 (3) Status: Ongoing

(4) Title: Evaluation of Thalassemia as Cause of Hypochromic Microcytic Anemia and in Interaction with Hemoglobin Variants

(5) Start Date: March 1978	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Nicholas C. Bethlenfalvay, MD, DAC	(8) Facility: FAMC
(9) Dept/Svc: Primary Care	(10) Assoc Investigators: Joseph Lima, DAC
(11) Key Words: Thalassemia-hemoglobin variants	

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 2/83 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: 3
d. Total Number of Subjects Enrolled to Date: 63
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".
None

(15) Study Objective:

To establish phenotype and genotype in patients with microcytic hypochromic anemia due to imbalance in globin chain synthesis.

(16) Technical Approach:
Patients with (a) hypochromic-microcytic anemai (b) patients whose hemoglobin electrophoretogram reveals a variant hemoglobin in amounts greater than 50 or less than 40% will be evaluated. Periperal blood will be incubated with 14_C leucine. Alpha/beta globin synthetic ratios will be calculated.

(17) Progress: Since the inception of the study, 63 patients were evaluated resulting in the identification of the following conditions: HbC/alpha thalassemia HbS/beta plus thalassemia HbS/beta 0 thalassemia, HbH disease, *2 cases of acquired HbH disease alpha-thalassemia - 1 and type II normal HbA_2 - beta plus thalassemia. Active consultation is provided, in selected case to the Staff Division of Hematology, University of Colorado Medical Center, Denver, under this protocol. In FY 1983 and in collaboration with investigators at the University of Oxford, U.K., and the University of California, San Francisco, work is continuing on the definition of the molecular lesion in the zeta-alpha globin gene complex of isolated chromosomes #16 of three patients who represent a new syndrome of hemoglobin H disease with mental retardation. In FY 84 work has been completed on a case

having a hitherto not described type of congenital dyserythropoietic anemia. The report of the case has been accepted by the British Journal of Haematology.

PUBLICATIONS:

1. Boehme WM, Piira TA, Kurnick JE and Bethlenfalvay NC: Acquired hemoglobin H in refractory sideroblastic anemia: A preleukemic marker. Arch Int Med, 138:603-606, 1978.

2. Weatherall DJ, Higgs DR, Bunch MB, Old JM, Hunt DM, Pressley L, Clegg JB, Bethlenfalvay NC, Sjolin S, Kiler RD, Magenis E. Francis JL and Bebbington, D: Hemoglobin H disease and mental retardation. A new syndrome or a remarkable coincidence? New Eng J Med 305:607, 1981.

PRESENTATIONS:

Bethlenfalvay, N.D., Hadnagy, C. and Heimpel, H.: Unclassified type of Congenital Dyserythropoietic Anemia: Evidence for a Disturbance of Red Cell Denucleation. Presented: 20th Annual Meeting of the Hungarian Society of Hematology, Szeged, Hungary, August 1984.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#:80/650 (3) Status:

(4) Title: The Ontogenesis of Hemoglobin in the American Opossum (Didelphis Virginia).

(5) Start Date: 18 March 1980	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Nicholas C. Bethlenfalvay, MD, DAC	(8) Facility: FAMC
(9) Dept/Svc: Primary Care	(10) Assoc Investigators:
(11) Key Words: Opossum Hemoglobin Red Cell Energy Metabolism Methemoglobin formation & reduction	J. E. Lima, DAC T. Waldrup, DAC
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 4/83 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

NA

(15) Study Objective:

This is a continuation of a previous Clinical Investigation study that was completed in June 1975. The overall objective is to follow and define the kinetics of methemoglobin reduction of opossum hemoglobin, in specific, as part of the overall energy metabolism of the red cell of this species.

(16) Technical Approach:

In-vivo and in-vitro reduction of nitrite induced methemoglobinemia will be followed hourly by quantitative, electrophoretic and spectroscopic means. Methemoglobin reductases will be quantitated and electrophoretically demonstrated, and compared to human reductases.

(17) Progress: Opossum Hb was found to oxidize faster than human Hb in solution, the converse was observed on inteact, glucose depleted erythrocytes even at acidic pH. Although opossum red cells were shown to be permeable to glucose, they did not require this substrate for methemoglobin reduction in-vitro methylene blue was found to accelerate methemoglobin reduction on intact opossum erythrocytes at a rate exceeding that seen in human erythrocytes. This reaction, in contrast, was shown to be dependent on glucose in the red cell environment. In FY 1983, work has been completed on the utilization of 6, 5 and 3 C carbohydrates and purine nucleosides as substrates for lactate and ATP in intact erythrocytes. The data were published in FY 1984. Quantitation of red

cell glycolytic intermediates, electrophoretic demonstration of adenosine deaminase and of purine nucleoside phosphorylase was accomplished. In preparation for HPLC analysis of catabolism of purine nucleotides as the putative energy source for methemoglobin reduction on glucose depleted erythrocytes, orienting experiments were performed utilizing various ensyme inhibitors to assess their ability to block this process.

PUBLICATIONS for FY 84 Annual Progress Report Proto No. 80/650

SERVICE Clinic DEPARTMENT Primary Care & Community Medicine

Petty C, Bethlenfalvay NC and Bageant T.: Spectrophotometric measurement of hemoglobin oxygen saturation in the Opossum, Didelphis Virginiana. Comp. Biochem. Physiol, 50:273, 1975.

Bethlenfalvay NC, Block, M and Brown GB: Hemoglobins of the Opossum (Didelphis Virginiana Kerr) I. Developmental changes from yolk sac to definitive erythropoiesis. Lab. Animal Sci, 26:106-165, 1976.

Bethlenfalvay NC, Brown GL and Waterman M: I. Hemoglobins of the Opossum (Didelphis Marsupialis) II. Electrophoretic and Chromatographic observations. Lab Animal Sci, 26:908-912, 1976.

John ME, Bethlenfalvay NC and Waterman MR: Oxidation - reduction properties of the hemoglobin of the opossum Didelphis Virginiana. Comp. Biochem. Physio. 73B:585-591, 1982.

Bethlenfalvay NC, Waterman MR, Lima JE and Waldrup T: Cystolic and membrane-bound methemoglobin reductases in erythrocytes of the opossum Didelphis Virginiana. Comp. Biochem. Physiol. 738:594, 1982.

Bethlenfalvay NC, Waterman MR, Lima JE, Waldrup T: Comparative aspects of methemoglobin foration and reduction in opossum Didelphis Virginiana and human erythrocytes. Comp. Biochem. Physiol. 75A:635-639, 1983.

Bethlenfalvay NC, Lima JE and Waldrup T: Studies on the energy metabolism of opossum (Didelphis Virginiana) erythrocytes. I. Utilization of carbohydrates and purine nucleosides.
Journal of Cellular Physiology. 120:69-74, 1984.

NURSING

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/700 (3) Status: Ongoing

(4) Title: A Comparison of Fluid Assessment Methods Utilizing Central Venous Pressure Versus Serum Osmolarity In Conjunction with Conventional Methods In Adults Undergoing Abdominal Surgery.

(5) Start Date: December 1983	(6) Est Compl Date: 15 October 1984
(7) Principal Investigator: Cynthia Bernard, CPT, ANC Michael Buxton, CPT, ANC James Eiring, CPT, ANC Donald Johnson, CPT, ANC Richard Palley, CPT, ANC Gregory Whitfield, CPT, ANC	(8) Facility: FAMC
(9) Dept/Svc: Nursing	(10) Assoc Investigators:
(11) Key Words: Comparison of Fluid Assessment Methods	None

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 40
d. Total Number of Subjects Enrolled to Date: 40
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: There is no difference in calculated intraoperative fluid requirements as determined by CVP and conventional methods versus serum osmolarity and conventional methods.

(16) The need for fluid replacement intraoperatively was made using the central venous pressure reading and other conventional fluid assessment parameters. Serum osmolarities were drawn during the surgical procedure and retrospectively evaluated to determine if serum osmolarities would provide a better means of calculating fluid replacement in the surgical patient.

(17) All data has been collected, statistical analysis of the data is in progress and the project will be completed by December 1984.

FAMC TENANT

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#:83/800 (3) Status: ongoing

(4) Title: The Health Evaluation Project (of the OCHAMPUS Employee Health Promotion Program)

(5) Start Date: March 1985	(6) Est Compl Date: September 1985
(7) Principal Investigator: William H. Hendrix, Ph.D. Associate Professor of Mgt. Clemson University Clemson, S.C.	(8) Facility: FAMC
(9) Dept/Svc: OCHAMPUS	(10) Assoc Investigators: Alex R. Rodriguez, M.D. CDR, MC, USN Medical Director
(11) Key Words: Health Promotion Wellness Production Emotional Exhaustion Job Satisfaction Somatic symptoms Stress	
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	(13) Est Accum OMA Cost:*

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 175

d. Total Number of Subjects Enrolled to Date: 235

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A (no drugs given)

(15) Study Objective:

The major objective is to establish what individual, organizational, and extra-organizational factors are predictive of stress, coronary artery disease potential, and desired organizational outcomes-i.e., increased productivity and decreased turnover and absenteeism. In turn, modification of these factors and their resulting effects will be assessed over time from the identified dependent variables (measured stress, indexed potential for developing CAD, and desired organizational outcomes).

(16) Technical approach: Evaluation of data will be in the form of path analyses to establish relationships between factors leading to stress and in turn to health-related and organizational factors. A pretest, post-test design is being used to establish effectiveness of interventions employed such as stress management and exercise.

CONTINUATION SHEET, FY 84 ANNUAL PROGRESS REPORT Proto No.: 83/800

Reporting Period: September 1983 to September 1984.

(1) There was a 25% withdrawal rate since the original evaluation March 1983.

(2) Preliminary findings indicate correlation between health promotion involvement and life stress, job stress, job satisfaction, commitment to work, absenteeism, and job performance. These correlations as well as indices of stress effects on health are provided (Encl 1).

(3) Although FAMC Management originally agreed to provide support service to draw blood during the period of this study, the service is not available for the two final make up sessions September 1984. This crisis situation was eventually resolved by agreement with Lowry Health Clinic.

PRESENTATIONS FOR FY 84 Annual Progress Report Proto No. 83/800

SERVICE N/A DEPARTMENT N/A

1. Hendrix, W.H., and Rodriquez, A.R.: Effects of Stress on Individual Productivity, Absenteeism, and Wellness. Presented: Ninth Biennial Psychology in the DOD Symposium, USAFA, Colorado, April 1984.

2. Hendrix, W.H., Rodriquez, A.R., and Presley, A.: Effects of Stress and Exercise on Employee Health. Presented: Fifth Annual Meeting of the Society of Behavioral Medicine, Philadelphia, Pa., May 1984.

3. Hendrix, W.H., Rodriquez, A.R., and Presley, A.: Job and Personal Factors Related to Job Stress and Risk of Developing Coronary Artery Disease. Presented: American Industrial Hygiene Conference, Detroit, Michigan, May 1984.

4. Hendrix, W.H., Rodriquez, A.R., and Presley, A.: Stress Effect on Organizational Outcomes and Prediction of CAD Risk. Presented: 92nd Annual American Psychological Association Convention, Toronto, Canada, August 1984.

5. Rodriquez, A.R., Iverson, D.C., Hendrix, W.H., Presley, A.: An Employee-Directed Wellness Project: Early Findings from the OCHAMPUS Health Promotion Program. Presented: American Public Health Association Meeting, Dallas, Texas, November 1983.

MEDDAC

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/902 (3) Status: Ongoing

(4) Title: Training Study, Emergency Medical Procedures

(5) Start Date: Nov 1982	(6) Est Compl Date: Indefinite
(7) Principal Investigator: MATTHEW J. WALSH, LTC, MC	(8) Facility: FAMC Ft Carson Veterinary Activity and Ft Carson MEDDAC Emergency Medical Service
(9) Dept/Svc: Emer Med & Vet	(10) Assoc Investigators: LTC David Roberts, MC
(11) Key Words: Emergency Medicine Procedures Animal Laboratory	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: N/A

d. Total Number of Subjects Enrolled to Date: N/A

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: This project is a refresher/teaching course in Emergency Medicine operative procedures. It is conducted on a quarterly basis for EMS physicians and PA's.

(16) Technical approach: Under general anesthesia animals are subjected to common Emergency Medicine operative procedures, including venous cutdown, peritoneal lavage, chest tube insertion, and thorocotomy with aortic cross clamp with cardiac laceration repair. At the end of the exercise, the animals are killed by lethal injection.

(17) Progress: This has been a beneficial exercise in maintaining physical skills in technical procedures done infrequently. These skills are essential for good patient care in true emergencies.

Publications and presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/903 (3) Status: Completed

(4) Title: Stabilization of Hemoglobins and Hematocrits in Females Traveling from Lower to Higher Elevations

(5) Start Date: May 1983	(6) Est Compl Date: May 1984
(7) Principal Investigator: Linda S. Wallace, CPT, ANC	(8) Facility: FAMC Fort Carson Army Hospital Fort Carson, CO
(9) Dept/Svc: OB-GYN & Pathology	(10) Assoc Investigators:
(11) Key Words: higher altitudes adaptation time hemoglobin level hematocrit level	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA

c. Number of Subjects Enrolled During Reporting Period: 58

d. Total Number of Subjects Enrolled to Date: 58

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To establish baseline hemoglobin and hematocrit levels of transcient (incoming) females both pregnant and nonpregnant at an altitude over one mile allowing for body compensation time and reinforce the time of stabilization. This would standardize care in as much as doctors could treat females with bleeding disorders and anemias in pregnancy with more consistency within a transcient population such as in the military as well as to note whether or not pregnant females require more time to adjust to the higher altitude since their bodies are under stress at this time.

(16) Technical Approach: Participants will be screened for eligibility before entering the study. Three hematological studies will be done: at time of entrance to study, at four to six weeks, and lastly at then to thirteen weeks. Results will be compared to findings from a Denver study documenting adjustment levels and rates for a predominantly male population.

(17) Progress: The study findings confirmed that adaptation progresses rapidly within the first three months and even leans toward a time frame within six weeks. The hemoglobin desplayed a 75% to 80% increase within the first six weeks after arrival at 6,000 feet. Between six weeks and three months the percent of increase was twenty to thirty-two. The hematocrit averges were a bit more puzzling. There was a definite increase of an averaged 1.88% point between the initial and second samplings. However,

KEY WORD INDEX

KEY WORD INDEX

INVESTIGATORS INDEX

INVESTIGATORS INDEX

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 82/950 (3) Status: ~~Terminated~~ Completed

(4) Title:

Case-Control Study of Invasive Cervical Cancer

(5) Start Date: June 1, 1982	(6) Est Compl Date: July 31, 1984
(7) Principal Investigator: David A. Savitz, Ph.D. Department of Preventive Medicine & Biometrics University of Colorado School of Medicine	(8) Facility: FAMC
(9) Dept/Svc: UCHSC	(10) Assoc Investigators: R. Hamman, M.D., Dept. Preventive Medicine & Biom. J. Berg, M.D., Department of Pathology University of Colorado School of Medicine
(11) Key Words: Cervical Cancer, Epidemiology	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: _____ b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 4

d. Total Number of Subjects Enrolled to Date: 10 from FAMC; 400 total

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

NONE

(15) Study Objective: Ascertain risk factors for cervical cancer including diet, smoking, sexual behaviors, sexually transmitted diseases, and oral contraceptives.

(16) Technical Approach: Case-control design comparing exposure histories of women with invasive cervical cancer, carcinoma in situ of the cervix, and healthy controls.

(17) Progress: The data collection ended July 31, 1984. The National Cancer Institute will provide us with a data type for analysis. We will send a summary of the study to all collaborating physicians and institutions when analyses are completed.

Publications and Presentations: None

CIVILIAN HOSPITALS

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#84/900 (3) Status: Terminated

(4) Title: Clinical Evaluation of AME Physio-Stim Therapy System

(5) Start Date: 1984	(6) Est Compl Date:
(7) Principal Investigator: Thomas A. Eskestrand, LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Ortho/Ft. Carson, CO	(10) Assoc Investigators:
(11) Key Words: electro-magnetic	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: - b. Review Results: -

c. Number of Subjects Enrolled During Reporting Period: -

d. Total Number of Subjects Enrolled to Date: -

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". -

(15) Study Objective: Application of an electro-magnetic field to the non-union site of a fracture of a bone in order to heal the fracture, or to heal a failed arthroesis.

(16) Progress: Principal Investigator has left the Army. The study was never started.

Publications and Presentations: none

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/905 (3) Status: Terminated
(4) Title: Cornonary Artery Disease

(5) Start Date: 1982	(6) Est Compl Date: May 1985
(7) Principal Investigator: Lytt Gardner, Ph.D. Matt Wayne Ledner, Ph.D., MC James Vogel, Ph.D. CPT Sandra Yaney, ANC (continued)	(8) Facility: FAMC Munson Army Community Hospital Ft. Leavenworth, KS Command & General Staff College Ft. Leavenworth, KS (continued)
(9) Dept/Svc: Cardiology/Medicine	(10) Assoc Investigators: MAJ Arden Ashton, MD, MC COL Julius Bedynek, MD, PhD., MC CPT Ernest Dagenhardt, ANC MAJ William Daniels, Ph.D., MSC (continued)
(11) Key Words: cardiovascular screening/CHD CAD	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Aug 83 b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: 927
d. Total Number of Subjects Enrolled to Date: 1,776
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective:
The purpose of this study is to detect previously unindentified cardiovascular disease in a young asymptomatic population, using a multistaged screening method.

Progress: The study was termined this year due to failure to report.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 84 (2) Protocol WU#: 83/904 (3) Status: Ongoing

(4) Title:

Activated Charcoal and Phototherapy in the Treatment of Neonatal Jaundice

(5) Start Date: August 1983	(6) Est Compl Date: December 1984
(7) Principal Investigator: Stephen Inscore, MD, CPT, MC	(8) Facility: FAMC Munson Army Hospital, Ft. Leavenworth, Ks Irwin Army Hospital, Ft. Riley, Ks
(9) Dept/Svc: Pediatric	(10) Assoc Investigators: Steven Eadline, MD, CPT, MC
(11) Key Words: charcoal phototherapy hyperbilirubinemia jaundice	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: May 84 b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: 2

d. Total Number of Subjects Enrolled to Date: 2

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: To examine the effectiveness that oral activated charcoal has in limiting the severity of nonphysiologic hyperbilirubinemia in otherwise normal newborns treated with phototherapy.

(16) Technical Approach: Term newborns who are otherwise normal except for nonphysiologic jaundice will be alternately placed into a group receiving phototherapy alone and in combination with charcoal. Parameters will be measured to determine in the combination of charcoal and phototherapy will enchance elimination of bilirubin.

(17) Progress: Too few numbers to derive any conclusions from, but no adverse reaction or complications noted thus far.

Publications and Presentations: none

there was a loss of 0.25% between the last two samplings.

The study relates time to physical adaptation, giving health care professionals better tools with whcih to evaluate the status of an individual who needs care and may have recently come into the area, or who may be in the area for a limited length of time.

Publications: Stabilization of Hemoglobins and Hematocrits in Females Travelling from a Lower to Higher Altitude. Submitted for publication

Presentations: Stabilization of Hemoglobins and Hematocrits in Females Travelling from a Lower to Higher Altitude. Presented: Nursing Research Symposium, 10-14 September 1984, Washington, D.C.

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